

# **EXHIBIT F**

Vladimir Iakovlev, M.D.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF VIRGINIA  
AT CHARLESTON

\*\*\*\*\* Master File No.  
IN RE: 2:12-MD-02327  
ETHICON, INC., PELVIC REPAIR MDL 2327  
SYSTEM PRODUCTS LIABILITY  
LITIGATION JOSEPH R. GOODWIN  
US District Judge

\*\*\*\*\*  
TONYA EDWARDS, ET AL,  
Plaintiffs, Case No.  
v. 2:12-CV-09972  
ETHICON, INC., ET AL,  
Defendants.

\*\*\*\*\*  
JO HUSKEY AND ALLAN HUSKEY,  
Plaintiffs, Case No.  
v. 2:12-CV-05201  
ETHICON, INC., ET AL,  
Defendants.

\*\*\*\*\*

DEPOSITION OF VLADIMIR IAKOVLEV, M.D.

Tuesday, March 18th, 2014

8:14 a.m.

Held At:

Hampton Inn Boston Logan Airport  
230 Lee Burbank Highway  
Revere, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

## Vladimir Iakovlev, M.D.

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<p>1 APPEARANCES:</p> <p>2 FOR THE HUSKEY PLAINTIFFS:</p> <p>3 ROBERT J. McCONNELL, ESQ.</p> <p>4 MOTLEY RICE LLC</p> <p>5 321 South Main Street</p> <p>6 Providence, Rhode Island 02903</p> <p>7 401-457-7700</p> <p>8 bmcconnell@motleyrice.com</p> <p>9</p> <p>10 FOR THE EDWARDS PLAINTIFFS:</p> <p>11 JOHN FABRY, ESQ.</p> <p>12 MUELLER LAW LLC</p> <p>13 404 W. 7th Street</p> <p>14 Austin, Texas 78701</p> <p>15 512-478-1236</p> <p>16 john.fabry@muellerlaw.com</p> <p>17</p> <p>18 FOR THE PLAINTIFFS:</p> <p>19 MARGARET M. THOMPSON, M.D., J.D.</p> <p>20 MOTLEY RICE LLC</p> <p>21 28 Bridgeside Boulevard</p> <p>22 Mt. Pleasant, South Carolina 29464</p> <p>23 843-216-9000</p> <p>24 mmthompson@motleyrice.com</p> <p>25</p>	<p>1 INDEX</p> <p>2 EXAMINATION PAGE</p> <p>3 VLADIMIR IAKOVLEV, M.D.</p> <p>4 BY MR. SNELL 5</p> <p>5 EXHIBITS</p> <p>6 NO. DESCRIPTION PAGE</p> <p>7 1 Notice of deposition..... 10</p> <p>8 2 Rule 26 Expert Report of Dr.</p> <p>9 Vladimir Iakovlev..... 60</p> <p>10 3 Document titled Facts of Data</p> <p>11 Considered in Forming Opinions..... 60</p> <p>12 4 Curriculum Vitae of Vladimir</p> <p>13 Iakovlev..... 60</p> <p>14 5 Chain of custody regarding Mrs.</p> <p>15 Edwards' mesh specimen, .....192</p> <p>16 6 Slide of paraffin blocks from Mrs.</p> <p>17 Edwards' explant.....214</p> <p>18 7 Slides of paraffin block of Ms.</p> <p>19 Edwards' explant.....214</p> <p>20 8 Pathology report in Ms. Edwards'</p> <p>21 case.....285</p> <p>22 9 Dr. Iakovlev's pathology report for</p> <p>23 Mrs. Edwards' specimen.....307</p> <p>24</p> <p>25</p>
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<p>1 APPEARANCES (Continued):</p> <p>2</p> <p>3 FOR THE DEFENDANTS:</p> <p>4 NILS B. SNELL, ESQ.</p> <p>5 BUTLER SNOW LLP</p> <p>6 500 Office Center Drive, Suite 400</p> <p>7 Fort Washington, Pennsylvania 19034</p> <p>8 267-513-1885</p> <p>9 burt.snell@butlersnow.com</p> <p>10 -and-</p> <p>11 M. ANDREW SNOWDEN, ESQ.</p> <p>12 BUTLER SNOW LLP</p> <p>13 150 3rd Avenue South, Suite 1600</p> <p>14 Nashville, Tennessee 37201</p> <p>15 615-651-6700</p> <p>16 andy.snowden@butlersnow.com</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 PROCEEDINGS</p> <p>2</p> <p>3 VLADIMIR IAKOVLEV, M.D.,</p> <p>4 having been first duly sworn, was examined and</p> <p>5 testified as follows:</p> <p>6 DIRECT EXAMINATION</p> <p>7 BY MR. SNELL:</p> <p>8 Q. State your full name for the record.</p> <p>9 A. Vladimir Iakovlev.</p> <p>10 Q. And, Doctor, you understand you're</p> <p>11 here today to take the deposition in the Huskey</p> <p>12 and Edwards cases that are currently pending in</p> <p>13 West Virginia --</p> <p>14 A. I do.</p> <p>15 Q. -- against Ethicon?</p> <p>16 A. I do.</p> <p>17 Q. All right. Have you had a -- taken a</p> <p>18 deposition before?</p> <p>19 A. Yes.</p> <p>20 Q. How many times?</p> <p>21 A. It was three times -- I mean two</p> <p>22 depositions, but one was split into two</p> <p>23 depositions.</p> <p>24 Q. Okay. And were those relatively</p> <p>25 recently?</p>

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<p>1 A. Yes.</p> <p>2 Q. All right. So you understand the</p> <p>3 rules of a deposition. The only thing I'll</p> <p>4 repeat or emphasize is if you don't understand a</p> <p>5 question, let me know, I'll do my best to</p> <p>6 rephrase it, repeat it, try to get to something</p> <p>7 you can answer. Okay?</p> <p>8 A. Okay.</p> <p>9 Q. What did you do today to prepare for</p> <p>10 your deposition?</p> <p>11 A. I reviewed my report.</p> <p>12 MR. SNELL: Off the record.</p> <p>13 (Off the record discussion.)</p> <p>14 BY MR. SNELL:</p> <p>15 Q. Is that the sum total of your</p> <p>16 preparation for your deposition, reviewing your</p> <p>17 report?</p> <p>18 A. Yes.</p> <p>19 Q. How long did you review your report</p> <p>20 for in preparation for your deposition?</p> <p>21 A. Last night, about two hours.</p> <p>22 Q. The Plaintiffs' lawyers who are here</p> <p>23 today, had you ever met them before this</p> <p>24 morning?</p> <p>25 A. Yes, I did.</p>	<p>1 A. About two hours.</p> <p>2 Q. Did it take place here at the Hampton</p> <p>3 Inn?</p> <p>4 A. Yes.</p> <p>5 Q. What did you do during the meeting</p> <p>6 with the Plaintiffs' attorneys, besides</p> <p>7 obviously talk with them?</p> <p>8 A. We reviewed the report, and we talked</p> <p>9 about the case.</p> <p>10 Q. Did you look at any other documents,</p> <p>11 any other materials besides your report?</p> <p>12 A. No. We mainly went through the list</p> <p>13 of references in the report.</p> <p>14 Q. You have in front of you some</p> <p>15 materials today. Is that your report?</p> <p>16 A. It's a copy of my report.</p> <p>17 Q. Color copy of your report?</p> <p>18 A. Yes.</p> <p>19 Q. All right. The two prior depositions</p> <p>20 you gave, what matters were those in?</p> <p>21 A. Well, the first part is my summary of</p> <p>22 my understanding of the processes which are</p> <p>23 happening when the mesh is placed in the body.</p> <p>24 And the second --</p> <p>25 Q. I'm going to stop you. I don't think</p>
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<p>1 Q. Did you meet with any Plaintiffs'</p> <p>2 lawyers in preparation for your deposition?</p> <p>3 A. No. I mean this -- I just met with</p> <p>4 these lawyers.</p> <p>5 Q. How long?</p> <p>6 A. How long what?</p> <p>7 Q. How long was the meeting?</p> <p>8 A. Yesterday?</p> <p>9 Q. I thought there wasn't a meeting</p> <p>10 yesterday. I thought the only thing you --</p> <p>11 MR. MCCONNELL: I think he</p> <p>12 misunderstood.</p> <p>13 A. I just misunderstood.</p> <p>14 Can you repeat the question?</p> <p>15 BY MR. SNELL:</p> <p>16 Q. Sure.</p> <p>17 Did you meet with any of the</p> <p>18 Plaintiffs' lawyers to prepare for your</p> <p>19 deposition?</p> <p>20 A. Yesterday. Yes, we did.</p> <p>21 Q. Yesterday or any day to prepare for</p> <p>22 this deposition today.</p> <p>23 A. We met yesterday.</p> <p>24 Q. Okay. How long did that meeting take</p> <p>25 place?</p>	<p>1 we're communicating.</p> <p>2 I believe you earlier testified you've</p> <p>3 given two prior depositions?</p> <p>4 A. Yes.</p> <p>5 Q. My question was; what types of matters</p> <p>6 or cases were those?</p> <p>7 A. Oh, previous depositions?</p> <p>8 Q. Yes.</p> <p>9 A. Mesh, transvaginal mesh litigations.</p> <p>10 Q. Against which manufacturer or doctors?</p> <p>11 A. Boston Scientific and AMS.</p> <p>12 Q. And when did you give that Boston</p> <p>13 Scientific deposition?</p> <p>14 A. January.</p> <p>15 Q. Of this year?</p> <p>16 A. Yes.</p> <p>17 Q. And the AMS deposition?</p> <p>18 A. February, and the second session was</p> <p>19 about two weeks ago.</p> <p>20 Q. February of 2014, March, 2014?</p> <p>21 A. Yes.</p> <p>22 Q. Have you given any other deposition</p> <p>23 testimony?</p> <p>24 A. No.</p> <p>25 Q. For the Boston Scientific deposition,</p>

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<p>1 do you know if that was also for West Virginia</p> <p>2 cases, or was that New Jersey, or some other</p> <p>3 state?</p> <p>4 A. There were three, I believe,</p> <p>5 litigation processes. One was West Virginia,</p> <p>6 one was Massachusetts.</p> <p>7 Q. And for AMS, do you have an</p> <p>8 understanding of where that litigation was that</p> <p>9 you were testifying in; West Virginia,</p> <p>10 Massachusetts, New Jersey?</p> <p>11 A. I'm not sure. I'm not sure. I don't</p> <p>12 want to confuse things.</p> <p>13 Q. I don't want you to guess. If you</p> <p>14 know you know, if you don't you don't.</p> <p>15 (Whereupon, Iakovlev Exhibit Number 1,</p> <p>16 Notice of deposition, was marked for</p> <p>17 identification.)</p> <p>18 BY MR. SNELL:</p> <p>19 Q. Doctor, I'm going to hand you a notice</p> <p>20 to take your deposition. Give counsel a copy</p> <p>21 (handing). This has been marked as Exhibit 1.</p> <p>22 Have you seen this document before?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And can you tell me the</p> <p>25 materials you brought in response to the notice</p>	<p>1 Do you have documents relating to</p> <p>2 fees, billing, or time spent in this litigation?</p> <p>3 A. I haven't billed for this litigation</p> <p>4 yet. It's pretty early, and I'm probably slow</p> <p>5 in billing. And I'm not sure if I can provide</p> <p>6 billing information for the other litigation.</p> <p>7 Q. Well, do you have billing information</p> <p>8 for the Boston Scientific information?</p> <p>9 A. As I said, no, I have not done billing</p> <p>10 for my -- for Boston Scientific work.</p> <p>11 Q. Have you done any billing information</p> <p>12 for -- strike that.</p> <p>13 Have you done any billing for AMS?</p> <p>14 A. Yes, I've done.</p> <p>15 Q. Did you bring that today?</p> <p>16 A. No, because I'm not sure if I can give</p> <p>17 it to you.</p> <p>18 Q. Well, the attorneys here would be able</p> <p>19 to let you know that. Your job as the witness</p> <p>20 is to bring materials, and if they have an</p> <p>21 objection they can pose their objection.</p> <p>22 MR. MCCONNELL: Well, you know --</p> <p>23 MR. SNELL: I'll just put on the</p> <p>24 record obviously --</p> <p>25 MR. MCCONNELL: You can put on the</p>
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<p>1 to take your deposition?</p> <p>2 A. I didn't bring anything except for the</p> <p>3 copy of my report.</p> <p>4 Q. Why not?</p> <p>5 A. Some questions were -- some items were</p> <p>6 so broad, or I wouldn't be able to bring them</p> <p>7 due to confidentiality issues or other issues.</p> <p>8 Q. Well, did you make any effort</p> <p>9 whatsoever to sit down and bring -- strike that.</p> <p>10 Did you make any effort whatsoever to</p> <p>11 bring any materials in response to the notice?</p> <p>12 A. I can provide the samples which were</p> <p>13 given to me within this litigation, remaining</p> <p>14 samples. I can provide that under my pictures.</p> <p>15 But I cannot provide patient material or</p> <p>16 patient -- the information containing</p> <p>17 confidential patient information.</p> <p>18 And some items were simply so broad,</p> <p>19 that incorporates whole my career, so I cannot</p> <p>20 do that.</p> <p>21 Q. Let's go through them one by one then.</p> <p>22 You're looking at Schedule A, item</p> <p>23 number 1, "All documents relating to fees,</p> <p>24 billing, or time spent in connection with your</p> <p>25 opinions in any pelvic mesh litigation."</p>	<p>1 record what you want.</p> <p>2 MR. SNELL: -- it goes to bias.</p> <p>3 MR. McCONNELL: I don't think -- our</p> <p>4 position is billing from other litigation</p> <p>5 against other Defendants is not producible. You</p> <p>6 can ask him particularly -- you can ask him</p> <p>7 approximately how much he may have billed. But</p> <p>8 the billing that he would send for other</p> <p>9 litigation is -- this litigation you have a</p> <p>10 right to, he hasn't done it. Other litigation,</p> <p>11 it's not producible.</p> <p>12 MR. SNELL: I mean our position is</p> <p>13 obviously it goes to bias. It is discoverable.</p> <p>14 And it's been requested to be produced, it's not</p> <p>15 here. So we'll take it up with the Court. And</p> <p>16 if -- you know, we're going to be seeing each</p> <p>17 other another day, so this is the least of my</p> <p>18 concerns.</p> <p>19 MR. FABRY: Can we have an agreement</p> <p>20 that if I object, or if Bob objects, that's good</p> <p>21 for both parties?</p> <p>22 MR. SNELL: Yes. I don't know who</p> <p>23 represents who.</p> <p>24 MR. FABRY: Tonya Edwards, John Fabry.</p> <p>25 MR. SNELL: And you are representing</p>

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<p>1 Huskey and Edwards?</p> <p>2 MR. FABRY: No, I'm representing Tonya</p> <p>3 Edwards.</p> <p>4 MR. McCONNELL: I'm representing</p> <p>5 Ms. Huskey, Bob McConnell.</p> <p>6 MR. SNELL: Of course, unless it's</p> <p>7 obviously specific to one of the --</p> <p>8 MR. FABRY: Understood.</p> <p>9 MR. SNELL: All right.</p> <p>10 MR. FABRY: We'll also object to the</p> <p>11 timing of this, of the notice.</p> <p>12 MR. SNELL: That's fine. I don't</p> <p>13 believe we got dates until very recently</p> <p>14 anyways, right?</p> <p>15 BY MR. SNELL:</p> <p>16 Q. How much time have you spent in this</p> <p>17 litigation, the Ethicon litigation?</p> <p>18 A. Specifically to prepare the report?</p> <p>19 Q. No, in total in the Ethicon</p> <p>20 litigation, how much time have you spent?</p> <p>21 A. Approximately it took me ten hours to</p> <p>22 prepare the report, analyze samples. Takes</p> <p>23 about two hours per sample. Maybe another three</p> <p>24 hours to work on pictures. And then on top of</p> <p>25 that, you have to add all time I spent in</p>	<p>1 sample?</p> <p>2 A. The report combines my knowledge of</p> <p>3 not just Ethicon meshes. Ethicon meshes were</p> <p>4 used to see if they follow the pattern and if</p> <p>5 they're the same findings. So specifically</p> <p>6 those samples were just six.</p> <p>7 But as I stated in the report, I</p> <p>8 examined 130 samples since the beginning of my</p> <p>9 interest in implantable meshes.</p> <p>10 Q. Have you prepared an invoice for the</p> <p>11 Ethicon litigation?</p> <p>12 A. No.</p> <p>13 Q. Estimate the total time -- strike</p> <p>14 that.</p> <p>15 Can you estimate for me how much you</p> <p>16 intend to charge for the Ethicon litigation if</p> <p>17 you were to submit a bill for all your time up</p> <p>18 until yesterday?</p> <p>19 A. So as I said, about ten hours for</p> <p>20 statement, six patients by two hours, 12. 22</p> <p>21 hours, 22, 25 hours.</p> <p>22 Q. Do you have a rate sheet, something</p> <p>23 that is written that documents how much you</p> <p>24 charge for your expert work?</p> <p>25 A. Yes, it's in there, it's 400. I don't</p>
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<p>1 researching implantable meshes in my career, so</p> <p>2 I don't know how far we can extend all that.</p> <p>3 Q. How much do you charge for report</p> <p>4 preparation?</p> <p>5 A. I charge \$400 per hour. \$400 per</p> <p>6 hour.</p> <p>7 Q. How much do you charge for giving a</p> <p>8 deposition?</p> <p>9 A. \$400 an hour.</p> <p>10 Q. How much do you charge for attending a</p> <p>11 trial?</p> <p>12 A. \$400 an hour.</p> <p>13 Q. And how many samples did you prepare</p> <p>14 in this Ethicon litigation?</p> <p>15 A. It's in the report. I believe it's</p> <p>16 six. So I had six TVT Ethicon slings,</p> <p>17 identified as Ethicon slings.</p> <p>18 Q. And so those are what you're referring</p> <p>19 to with regard to two hours per sample?</p> <p>20 A. Any. Any mesh sample would take me,</p> <p>21 for thorough examination, about two hours.</p> <p>22 Q. Okay.</p> <p>23 A. Including Ethicon or any other.</p> <p>24 Q. So for the Ethicon litigation, how</p> <p>25 many samples have you studied at two hours per</p>	<p>1 have a scale for different procedures. \$400</p> <p>2 flat rate, 400 an hour flat rate.</p> <p>3 I am not making a living as an expert.</p> <p>4 I have no -- I had no knowledge about litigation</p> <p>5 when I started working on meshes. My main work</p> <p>6 is diagnostic work at the hospital, and academic</p> <p>7 work, research, teaching.</p> <p>8 MR. SNELL: Just note on the record</p> <p>9 request to produce AMS; request to produce</p> <p>10 Boston Scientific.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. This asked for an updated CV. I know</p> <p>13 there's a CV attached to your report, that was</p> <p>14 produced with your report. Is that current as</p> <p>15 we sit here today?</p> <p>16 A. Yes, it is current.</p> <p>17 Q. No more publications or anything like</p> <p>18 that?</p> <p>19 A. Nothing.</p> <p>20 Q. "All documents" -- Number 3, all</p> <p>21 documents prepared by you or at your direction</p> <p>22 in connection with your expected testimony, or</p> <p>23 the development of your opinion or belief, and</p> <p>24 assessment or determination of facts relating to</p> <p>25 this and any other pelvic mesh cases.</p>

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<p>1 A. Everything I put for this case, for 2 this litigation, is in the report. All pictures 3 and everything I prepared is in the report. I 4 may produce something else for the trial if it 5 goes for trial, but I don't have it right now. 6 Q. What may you produce for the trial? 7 A. Maybe larger picture, or a model, 8 something like that, for demonstration purposes. 9 Q. Your report has photographs of some of 10 the pathology specimens in Mrs. Edwards' case, 11 correct? 12 A. Yes. Yes. Edwards had pictures. 13 Yes. 14 Q. Specifically if we turn to the back, 15 towards the back, there's a series of 16 photographs that begin on Page 58 labeled TE1. 17 A. Mm-hmm. 18 Q. And they run to Page 71 ending at 19 Figure TE10b? 20 A. Yes. 21 Q. Are those all of the photographs that 22 you took of the pathology in Mrs. Edwards' case? 23 A. Most likely. I could have taken 24 several shots and just different exposure or 25 something, yeah.</p>	<p>1 A. They're just copy of the same image. 2 BY MR. SNELL: 3 Q. But they would be at different power 4 levels? 5 A. Yes. Or focusing, maybe I didn't like 6 the focusing, so refocused. 7 Q. They may be of a different part of the 8 specimen? 9 A. Possible. I don't remember now. 10 Q. Okay. 11 A. I could have taken the same feature, 12 like a muscle. I see muscle here, I see muscle 13 there, but then again I cannot end up with 300 14 pictures in my report. 15 Q. But you didn't bring them here today? 16 A. No. 17 MR. SNELL: So request to produce 18 those. 19 BY MR. SNELL: 20 Q. And please preserve the metadata on 21 those. Do you know what that is? How about; 22 I'd like to request electronic copies of those, 23 if that's okay. 24 A. Sure. You mean raw files? 25 Q. Native files.</p>
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<p>1 Q. So you could have taken other 2 photographs, but these are the ones you decided 3 to include in your report? 4 A. Yes. Well, I can take endless number 5 of pictures. These were taken to demonstrate my 6 findings, my conclusions, not to document the 7 case. These are demonstrations. 8 Q. Did you take any other photographs of 9 Mrs. Edwards' pathology specimens that were not 10 put into your report? 11 A. As I said, I could have taken 12 different frames or exposures. I have raw 13 files. As a photographer you take several 14 shots, and then you pick the best one. 15 Q. I understand that. 16 So did you bring those additional 17 photographs today? 18 A. No. 19 Q. Do you have them on your computer 20 somewhere in Toronto? 21 A. They're saved, yes. 22 Q. I'm sorry? 23 A. They're saved on the hard drive, yes. 24 Q. So why didn't you bring those? 25 MR. McCONNELL: Objection.</p>	<p>1 A. Okay. Sure. 2 Q. Did you personally take the 3 photographs? 4 A. Yes. 5 Q. Okay. Have you selected any 6 photographs for trial that you plan to blow up 7 or, you know, make larger? 8 A. No. 9 Q. You said a model. What type of model 10 are you talking about that you may produce for 11 trial? 12 A. Like a three-dimensional model just to 13 show how mesh looks under microscope, because 14 it's hard for people to understand 15 two-dimensional cuts of a three-dimensional 16 structure. 17 Q. Have you prepared this 3D model? 18 A. No. 19 Q. Have you prepared it for any other 20 litigation? 21 A. No. 22 Q. What software would you use to prepare 23 the 3D model? 24 A. I don't know yet. But I mean I was 25 thinking about a simple, not a software model,</p>

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<p>1 but simple actual model, physical, out of like 2 cables. 3 Q. You mentioned cables. What type of 4 cables? 5 A. Any round structure with enough 6 stiffness to simulate the polypropylene filament 7 so it holds the shape. 8 Q. Are you referencing like a metal 9 cable? 10 A. No. But I'm referencing cables with 11 plastic insulation, so it would be about the 12 same stiffness. Or it can be hose, it doesn't 13 have to be a cable. 14 MR. McCONNELL: Go off the record for 15 just a second. 16 (Off the record discussion.) 17 BY MR. SNELL: 18 Q. So we have -- this is your final 19 report, and your only report? 20 A. Yes. 21 Q. Did you prepare any reports for the 22 other litigations, the AMS or Boston Scientific 23 litigations? 24 A. Yes, I did. 25 Q. Did you bring those here today?</p>	<p>1 about whether or not you could produce these 2 materials that you didn't bring but which you 3 have? 4 A. Yes, we discussed this. 5 Q. When? 6 A. We discussed this yesterday. 7 Q. Yesterday when you were here in 8 Boston? 9 A. Yes. 10 Q. Where did you come from to get to 11 Boston? 12 A. Toronto. 13 Q. You came in yesterday, then, from 14 Toronto? 15 A. Yes. 16 Q. The tests that you did in this 17 litigation, can you tell me what those were? 18 A. What do you define, "test"? Test is a 19 pathological examination, it's microscopic 20 images and microscopic descriptions, tests of 21 physical device, of a new device, it's also in 22 the -- described in the report. 23 Q. So the tests done in this litigation 24 are you reviewed pathologic specimens and 25 analyzed them, correct?</p>
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<p>1 A. No. Because I don't know if I can 2 give it to you, because it's for different 3 litigation. 4 MR. SNELL: Request to produce. 5 BY MR. SNELL: 6 Q. Do you have any electronic files or 7 any electronic documents that you brought 8 responsive to this schedule that you're holding 9 now that you haven't given to me? 10 A. No. 11 Q. You don't have any thumb drives, any 12 DVDs or CDs that have any materials that are 13 responsive? 14 A. No. 15 Q. Number 5 is "Any reports or other 16 documentation concerning testing done by you in 17 connection with this or other pelvic mesh case." 18 A. What I've done for this litigation is 19 in my report. What I've done for other 20 litigation is in their corresponding reports. 21 And again, I'm not sure if I can give them to 22 you because they're for different litigation. 23 They contain names of the patients. I'm always 24 concerned with confidentiality. 25 Q. Did you talk to any of the attorneys</p>	<p>1 A. Yes. 2 Q. And then you also did some analyses on 3 a piece of mesh that had not been implanted, 4 correct? 5 A. Yes. 6 Q. And those are contained within your 7 report? 8 A. Yes. 9 Q. For example, you took, if I recall, 10 some SEMs of a piece of mesh that was not 11 implanted, correct? 12 A. SEM, I don't -- 13 Q. Electron microscopy? 14 A. Not scanning. 15 Q. Not scanning. Let me take that back. 16 You did some electron microscopy on a 17 piece of mesh that had not been implanted in a 18 human being, correct? 19 A. No, I have not done that. 20 Q. You haven't done that? 21 A. I only did conventional histology on 22 the piece of mesh which had been exposed to 23 formalin and routine processing procedures, but 24 I have not done electron microscopy the same 25 way.</p>

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<p>1 Q. You did electron microscopy on mesh</p> <p>2 that had been implanted in tissue?</p> <p>3 A. Yes. Implanted and explanted,</p> <p>4 transmission electron microscopy.</p> <p>5 Q. Did you do any other types of testing?</p> <p>6 A. Well, I've done transmission electron</p> <p>7 microscopy. I've done routine histology which</p> <p>8 involves several stains, and polarization. And</p> <p>9 I examined new sample, Boston Scientific, and</p> <p>10 actually other manufacturer devices. Yeah,</p> <p>11 that's it.</p> <p>12 Q. You didn't do, for example, FTIR</p> <p>13 testing, correct?</p> <p>14 A. It's not within my expertise. I don't</p> <p>15 even know what it is.</p> <p>16 Q. Okay. But it's not something you did?</p> <p>17 A. (Nodding in the negative).</p> <p>18 Q. Correct?</p> <p>19 A. I didn't.</p> <p>20 Q. You didn't do any chemical analyses on</p> <p>21 any of the specimens, correct?</p> <p>22 A. You have to define what is chemical</p> <p>23 analysis. There is a specific test, if we put</p> <p>24 chemical analysis, if I stain it with</p> <p>25 histological stain is it chemical analysis, if I</p>	<p>1 A. The specimen was divided. There was</p> <p>2 one part which was preserved in glutaraldehyde,</p> <p>3 it's a type of fixative for electron microscopy;</p> <p>4 and the other piece went to formalin, which is</p> <p>5 fixative for histology. Formalin is standard</p> <p>6 fixative in all samples. All of the samples</p> <p>7 came to me in formalin already. These are</p> <p>8 routine diagnostic procedures, routine</p> <p>9 diagnostic reagents.</p> <p>10 Then after fixation, the samples are</p> <p>11 being processed to be imbedded in formalin --</p> <p>12 sorry, paraffin, and then paraffin blocks a</p> <p>13 section to produce 4-micron thick sections on</p> <p>14 glass slides, and then tissue can be stained.</p> <p>15 Initial staining is hematoxylin and eosin, which</p> <p>16 is agent E, and then immunohistochemical stains</p> <p>17 can be used as well as histochemical stains,</p> <p>18 specifically for meshes. Immunohistochemical</p> <p>19 stains for muscle can be used to identify</p> <p>20 muscles, immunostain for S100 protein to help</p> <p>21 identification of peripheral nerve branches.</p> <p>22 I've also done staining for calcium,</p> <p>23 trichrome stains, which I didn't do for Ethicon,</p> <p>24 but I've done it for other meshes.</p> <p>25 And then when the stains are completed</p>
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<p>1 polarize it in microscope is it a chemical or</p> <p>2 not? I can tell you exactly what I've done and</p> <p>3 what I haven't done.</p> <p>4 Q. Okay. Let's just get to that. And</p> <p>5 tell me exactly what you did.</p> <p>6 A. So for transmission electron</p> <p>7 microscopy the tissue is being imbedded in the</p> <p>8 plastic and sectioned, and then it's being</p> <p>9 examined under transmitted electron beam to see</p> <p>10 ultra structures. So essentially you examine it</p> <p>11 by visual features, you identify structures</p> <p>12 which are visible by the electron beam. There</p> <p>13 is no specific stain. There's no specific</p> <p>14 stain, it's heavy metal, and that's it.</p> <p>15 For histology, the samples are fixed</p> <p>16 in formalin, which came to me fixed in formalin,</p> <p>17 except for one specimen which was in</p> <p>18 St. Michael's, and it was St. Michael's patient,</p> <p>19 and that specimen went directly to</p> <p>20 glutaraldehyde for electron microscopy. And --</p> <p>21 Q. I'm going to stop you right there. I</p> <p>22 just want to make sure I get this.</p> <p>23 The specimen from the St. Michael's</p> <p>24 patient, you said that specimen went directly to</p> <p>25 what?</p>	<p>1 they can be examined in the microscope. And</p> <p>2 again, there is a visual detection of present or</p> <p>3 absent staining, or of it's specificity and then</p> <p>4 interpretation. This is a routine diagnostic</p> <p>5 procedure. That's how it's done.</p> <p>6 Q. When you say this process in the</p> <p>7 review of the histologic slides is a routine</p> <p>8 diagnostic procedure, when you say that you mean</p> <p>9 that's a routine diagnostic procedure for a</p> <p>10 pathologist like yourself?</p> <p>11 A. Yes, for an anatomical pathologist.</p> <p>12 And for new mesh, because I've observed several</p> <p>13 changes in the body and changes in the mesh, I</p> <p>14 examine new mesh just to understand why there's</p> <p>15 curving, why there's curling, and the pattern of</p> <p>16 the weave, and its flexibility, because I</p> <p>17 examine also tissues for their firmness, so I</p> <p>18 need compare what's the firmness of the new mesh</p> <p>19 without the scar before implantation.</p> <p>20 Again, this is something I would do</p> <p>21 for other implantable devices if I have a</p> <p>22 question of how the changes happen.</p> <p>23 Q. You looked at the pattern weave in</p> <p>24 some of the meshes, correct?</p> <p>25 A. Yes.</p>

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<p>1 Q. Do you have any formal training in</p> <p>2 textiles?</p> <p>3 A. No.</p> <p>4 Q. Do you have any formal training in how</p> <p>5 meshes are either woven or knitted together?</p> <p>6 A. No.</p> <p>7 Q. Have you ever been involved in the</p> <p>8 weaving or knitting of a mesh?</p> <p>9 A. No.</p> <p>10 Q. Do you consider yourself a textile</p> <p>11 expert?</p> <p>12 A. No. I'm also not expert in pacemakers</p> <p>13 or cardiac volumes, but when they come out of</p> <p>14 the body they come to me. The same thing with</p> <p>15 knee implants and hip implants. Everything</p> <p>16 which is taken out of human body or taken off a</p> <p>17 human body at time of death comes for a</p> <p>18 pathology co-examination, so we have to</p> <p>19 correlate the devices with the changes in the</p> <p>20 body, and this part of our training as</p> <p>21 pathologists.</p> <p>22 Q. One of the things you mentioned was</p> <p>23 you examined the tissues for their firmness when</p> <p>24 the mesh was in them, correct?</p> <p>25 A. Yes.</p>	<p>1 before, that was within the range of normal.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. What's the firmness of normal tissue?</p> <p>4 A. It's a tactile memory, I cannot</p> <p>5 explain it.</p> <p>6 Q. How do you measure this firmness?</p> <p>7 A. There is no numerical measurement. We</p> <p>8 just touch and go by touch.</p> <p>9 Q. Is there any objective methodology by</p> <p>10 which you can ascertain the firmness of tissue?</p> <p>11 A. No. As I said, there is no numerical</p> <p>12 volumes. But it's how it's done, it's the</p> <p>13 practice of pathologists. For example, breast</p> <p>14 cancers, we palpate, we find the edges, and then</p> <p>15 there is measurement taken from firm edges, and</p> <p>16 that's how millions of women are treated, either</p> <p>17 treated by chemotherapy or not, just by patient.</p> <p>18 Q. What type of measurement is taken from</p> <p>19 the edges?</p> <p>20 A. Length. Linear measurements.</p> <p>21 Q. They're not using some type of</p> <p>22 compression or calibration instrument to test</p> <p>23 the firmness or hardness of the tissue, correct?</p> <p>24 A. No, there is not.</p> <p>25 Q. And there's nothing like that for the</p>
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<p>1 Q. Let's talk about Mrs. Edwards' case.</p> <p>2 You don't know what the firmness of</p> <p>3 her tissues were before she had the mesh put in,</p> <p>4 correct?</p> <p>5 A. I know what's the firmness of tissue</p> <p>6 in general human tissue when it's taken out, so</p> <p>7 every time the sample -- well, I mean I see</p> <p>8 where you're going, so I don't want you to</p> <p>9 misrepresent my answer.</p> <p>10 Q. I want an accurate answer to my</p> <p>11 question, not where you think I'm going to go.</p> <p>12 Because I'm going to get to what you looked at</p> <p>13 and how you handled it for Mrs. Edwards and all</p> <p>14 of that.</p> <p>15 All right. You personally do not know</p> <p>16 the firmness of her tissues before she had the</p> <p>17 mesh put in, correct?</p> <p>18 MR. McCONNELL: Object to your leading</p> <p>19 question.</p> <p>20 MR. SNELL: I'm allowed to lead, he's</p> <p>21 adverse to me.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. Go ahead.</p> <p>24 A. I didn't, no. I know what normal</p> <p>25 tissue firmness is. And if it was normal</p>	<p>1 tissues that Mrs. Edwards had explanted with the</p> <p>2 mesh, correct?</p> <p>3 A. No. The only measurements in</p> <p>4 pathology are taken weight and length and volume</p> <p>5 in diagnostic -- routine diagnostic pathology.</p> <p>6 Q. The trichrome staining that you could</p> <p>7 do, is it your testimony that you did not do</p> <p>8 that for the Ethicon meshes?</p> <p>9 A. Yes, I did not do it specifically for</p> <p>10 Ethicon meshes.</p> <p>11 Q. You didn't do any trichrome staining</p> <p>12 on Mrs. Edwards' specimens, correct?</p> <p>13 A. No.</p> <p>14 Q. No, I'm not correct, or --</p> <p>15 A. No, I didn't do it for Mrs. Edwards.</p> <p>16 Q. Okay. You mentioned a staining for</p> <p>17 detection of calcium. Was that the trichrome</p> <p>18 you were talking about?</p> <p>19 A. No, it's a different stain.</p> <p>20 Q. What stain is that?</p> <p>21 A. von Kossa.</p> <p>22 Q. von Kossa?</p> <p>23 A. von Kossa, double S-A.</p> <p>24 Q. Did you do any von Kossa staining?</p> <p>25 A. von Kossa. No, not for Ms. Edwards.</p>

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<p>1 The stain is showing if there is calcium in the 2 tissue, so pretty much all fragile, brittle 3 tissues in human body contain calcium, that's 4 why they're brittle. I saw that the bark is 5 cracking, so my question is it because of 6 calcium inclusion, and that's why I did calcium 7 staining. And it wasn't -- didn't contain any 8 calcium.</p> <p>9 Q. Did you do any calcium staining in 10 Mrs. Edwards' tissues?</p> <p>11 A. No.</p> <p>12 Q. Did you do any calcium staining on the 13 Ethicon -- other Ethicon TVT meshes?</p> <p>14 A. I'm not sure now. I would have to 15 look. Because I've done it in some samples, 16 some could have been TVT.</p> <p>17 Q. How would you go about checking to see 18 whether --</p> <p>19 A. I can check. The slide is in my 20 office, the slides are in my office.</p> <p>21 Q. So you have some slides in your office 22 which contains pathology specimens that were 23 stained for calcium that you could check?</p> <p>24 A. Yes.</p> <p>25 Q. And as you sit here right now, you</p>	<p>1 you're referring to, or is it a series of 2 documents that contain the histology findings, 3 the patient demographics, and other material?</p> <p>4 A. Each specimen which comes to 5 St. Michael's Hospital is processed as patient 6 sample, immediately becomes St. Michael's 7 patient. So demographics is reported in the 8 system; patient date of birth, procedure date. 9 Then gross examination is recorded, or gross 10 pictures are being stored in the hard drives. 11 All stains are recorded in the laboratory 12 information system. Then the report is being 13 generated, I sign out the report. And then for 14 publication purpose, I summarize this in 15 spreadsheets.</p> <p>16 Q. Those would be like Microsoft Excel 17 spreadsheets?</p> <p>18 A. Yes.</p> <p>19 Q. Is that the program you used, or is it 20 some other program?</p> <p>21 A. It's Excel.</p> <p>22 Q. And you didn't bring any of those 23 materials, obviously?</p> <p>24 A. As I said, it, first of all, contains 25 patient confidential information. Second, it's</p>
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<p>1 don't know whether those were for the TVT-O mesh 2 or some other manufacturer's mesh?</p> <p>3 A. No, I don't remember now. These 4 meshes are very similar, they have exactly the 5 same patterns, there's no need of repeating 6 stain, because we see many specimens.</p> <p>7 Q. If the slides in your office, the 8 calcium staining slides, let's say if somehow 9 they were lost or damaged or destroyed, would 10 you have a way of knowing what they showed?</p> <p>11 A. I examined them. I would remember 12 them. And I took at least one picture to 13 document that it's not there.</p> <p>14 Q. Did you make any -- did you record or 15 write down anywhere what you saw on the calcium 16 staining?</p> <p>17 A. Calcium stain, no, but some 18 information is recorded.</p> <p>19 Q. What information is recorded with 20 regard to your review of explanted meshes?</p> <p>21 A. My histological findings, patient 22 demographics. And it's confidential, so I 23 cannot release it, and privileged because it's 24 in preparation for publication.</p> <p>25 Q. What type of document is this that</p>	<p>1 in preparation for publication, and it's my 2 personal research.</p> <p>3 Q. So it's in preparation.</p> <p>4 You say it's your personal research, 5 but it's research that you're deriving opinions 6 from, correct?</p> <p>7 A. Yes. But I meant personal, I am as a 8 principal investigator. Personal not for home 9 use, but meant that I'm principal investigator 10 in the project.</p> <p>11 Q. And part of what goes into you 12 formulating your opinions is your experience 13 with these materials, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Have you submitted any analyses for 16 publication?</p> <p>17 A. It's in preparation and at submission 18 stages, in pre-submission inquiries.</p> <p>19 Q. So your analyses have not been 20 submitted to a particular journal yet, is that 21 what you're telling me?</p> <p>22 A. Pre-submission inquiries, yes. For 23 manuscripts specifically for transvaginal meshes 24 have not been submitted yet.</p> <p>25 Q. When you say "pre-submission</p>

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<p>1 inquiries," I don't understand that, so explain</p> <p>2 what that means?</p> <p>3 A. You write a short paragraph with a</p> <p>4 letter to editor asking if the journal would be</p> <p>5 interested in this type of publication.</p> <p>6 Q. Okay.</p> <p>7 A. Journals, they have very different</p> <p>8 requirements, and it takes a month to prepare</p> <p>9 the manuscript. You submit it, it gets</p> <p>10 rejected. It just saves you time to send</p> <p>11 pre-submission inquiry.</p> <p>12 Q. So you write essentially a paragraph</p> <p>13 to say "here's what we did, are you interested</p> <p>14 in moving to the next step?"</p> <p>15 A. Yes.</p> <p>16 Q. And can you tell me the journals that</p> <p>17 you've done that for?</p> <p>18 A. I cannot tell you because it's</p> <p>19 privileged.</p> <p>20 Q. Privileged under what?</p> <p>21 A. Maybe you will try to contact the</p> <p>22 journal and stop my publication.</p> <p>23 Q. What I'm asking you; what's your</p> <p>24 understanding of why it's privileged? I'm not</p> <p>25 interested in contacting the journal or trying</p>	<p>1 States or international, Canada? Where are they</p> <p>2 at?</p> <p>3 A. They are all international.</p> <p>4 Headquarters, I think at least for two, are in</p> <p>5 UK.</p> <p>6 Q. The Excel spreadsheets that you</p> <p>7 referenced, are those on your personal computer,</p> <p>8 or some other computer system?</p> <p>9 A. They're backed up in the hard drives</p> <p>10 of St. Michael's Hospital. I do have them on my</p> <p>11 research laptop. I mean depending on the</p> <p>12 version, because it's getting updated here and</p> <p>13 there. Yes, that's -- for pathology reports,</p> <p>14 they are all in the hospital system.</p> <p>15 Q. And just so I'm clear, you have not</p> <p>16 drafted a full manuscript for this research that</p> <p>17 you're doing?</p> <p>18 A. For transvaginal meshes, no, it's not</p> <p>19 completed yet. And it will be more than one</p> <p>20 manuscript.</p> <p>21 MR. SNELL: Note request to produce on</p> <p>22 the calcium staining.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. I believe you also mentioned the</p> <p>25 immunohisto staining S100?</p>
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<p>1 to stop what you're doing, I'm just</p> <p>2 understanding; why do you believe it's</p> <p>3 privileged?</p> <p>4 A. Because people can contact the</p> <p>5 journals. People can and people have done it,</p> <p>6 they've blocked publications. There's a whole</p> <p>7 process how to avoid that.</p> <p>8 The manuscripts are anonymized,</p> <p>9 reviewers don't see the names, reviewers don't</p> <p>10 see the institutions. You can even select</p> <p>11 specific reviewers as not being used as</p> <p>12 reviewers. Because this issue came up lately</p> <p>13 that if the manuscript's work is exposed before</p> <p>14 it gets published, it can be either copied,</p> <p>15 plagiarized, or stopped from publication.</p> <p>16 Q. How many journals have you -- so</p> <p>17 you're not going to tell me the names of the</p> <p>18 journals that you did the pre-submission --</p> <p>19 A. (Nodding in the negative).</p> <p>20 Q. -- inquiries, correct?</p> <p>21 A. No.</p> <p>22 Q. How many journals were there that</p> <p>23 you've done for pre-submission inquiries?</p> <p>24 A. Three.</p> <p>25 Q. Are those journals in the United</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. And does that -- that stain is</p> <p>3 to look for proteins? Strike that.</p> <p>4 What does S100 stain for?</p> <p>5 A. All immunohistochemical stains, the</p> <p>6 staining specific protein in the -- sort of</p> <p>7 simplified way of saying it -- the antibodies</p> <p>8 being developed against the specific protein.</p> <p>9 So that protein can be introduced into mouse,</p> <p>10 mouse develops antibodies against the protein,</p> <p>11 or a culture of cells develops antibodies</p> <p>12 against the protein. Then these antibodies are</p> <p>13 being extracted. And then if you apply these</p> <p>14 antibodies against tissue, they bind to that</p> <p>15 specific protein. Then if you have -- initial</p> <p>16 animal is mouse, and then you have antibodies</p> <p>17 against mouse immunoglobulin, then you can bind</p> <p>18 those antibodies over.</p> <p>19 But the second set of antibodies are</p> <p>20 conjugated with dye, brown dye, or through other</p> <p>21 mechanism becomes brown, and this way you can</p> <p>22 actually see where the initial target protein is</p> <p>23 in the tissue. It's a bit complex. It's easier</p> <p>24 to draw, but that's how it is.</p> <p>25 Q. If I had a sheet of paper, could you</p>

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<p>1 draw what you're referencing?</p> <p>2 A. Yes.</p> <p>3 So assume we have -- somebody was</p> <p>4 smart enough to figure out that there is a</p> <p>5 protein and he calls it S100, or he can call it</p> <p>6 Bobby or whatever, I mean the researchers</p> <p>7 sometimes comes up with funny names. So this is</p> <p>8 S100 protein, and we know this is S100 protein.</p> <p>9 So this protein is introduced in</p> <p>10 mouse. So mouse, because it's a foreign protein</p> <p>11 for the animal, develops antibody against S100</p> <p>12 protein. So the antibody (drawing), light chain</p> <p>13 looks like letter Y, just draw it like Y. So</p> <p>14 mouse immune system develops immunoglobulin</p> <p>15 which binds against S100 protein.</p> <p>16 Q. Can I stop you?</p> <p>17 The immunoglobulin that the mouse</p> <p>18 develops, is that the antibody that -- is that</p> <p>19 the antibody, or are they two different things?</p> <p>20 A. That's antibody. Immunoglobulin is</p> <p>21 antibody. I mean, yes, antibody and</p> <p>22 immunoglobulin, we can say that they are the</p> <p>23 same thing.</p> <p>24 So then if you kill the mouse, draw</p> <p>25 serum, and then we have human tissue on the</p>	<p>1 primary antibody, and will show as a brown</p> <p>2 color. This one is colorless, this one will</p> <p>3 have a color.</p> <p>4 Technically you can attach dye here</p> <p>5 and then just see the antibody. But this will</p> <p>6 be only very small signal, you may not be able</p> <p>7 to see it. This way you can have several</p> <p>8 antibodies stuck to primary antibody, so your</p> <p>9 signal gets larger and you can see it easier.</p> <p>10 Q. So the several antibodies stuck to the</p> <p>11 primary antibody that's on the tissue slides of</p> <p>12 the human that you're referring to?</p> <p>13 A. So this amplifies, instead of one</p> <p>14 point you end up with several points.</p> <p>15 Q. And then the color that it stains for</p> <p>16 S100 is brown that you referenced?</p> <p>17 A. For what I use is brown. Sometimes if</p> <p>18 you use different reagents it can be purple,</p> <p>19 red.</p> <p>20 Q. Is there a certain brand or type of</p> <p>21 S100 that you use?</p> <p>22 A. It's in the records for immuno -- as I</p> <p>23 said, we are diagnostic lab, everything is</p> <p>24 quality controlled and quality assurance, and</p> <p>25 each new vial is being optimized and</p>
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<p>1 slide.</p> <p>2 Now, then, if we take this antibody or</p> <p>3 immunoglobulin and introduce it to a rabbit, so</p> <p>4 this antibody goes into rabbit, and then this is</p> <p>5 a mouse antibody, so let's make a thick dark so</p> <p>6 we can (drawing) -- rabbit's immune system</p> <p>7 develops antibodies against mouse antibodies,</p> <p>8 and let's put it empty sort of clear like this</p> <p>9 (drawing).</p> <p>10 Then what we have, we have rabbit</p> <p>11 anti-mouse immunoglobulin. And then this</p> <p>12 antibody can be also conjugated to specific</p> <p>13 molecules which can be further amplified to</p> <p>14 brown stain.</p> <p>15 So now we have one vial of rabbit</p> <p>16 anti-mouse antibodies, and we have mice, and</p> <p>17 then we can introduce different proteins into</p> <p>18 the mice, and then we can have one rabbit</p> <p>19 antibody with the dye, and a whole set of</p> <p>20 different antibodies from the mouse against</p> <p>21 human proteins. This gives you flexibility.</p> <p>22 You apply first antibody, it binds</p> <p>23 here because it's specific against human</p> <p>24 protein. But then you have universal detection</p> <p>25 system, or dye, which will stick to the first</p>	<p>1 standardized. It's in the records. I can check</p> <p>2 what they used.</p> <p>3 Q. Okay. So just to be clear, the S100</p> <p>4 stain that you used, somewhere it's recorded</p> <p>5 what that S100 stain was and when it was used?</p> <p>6 A. Yes. It's vial, the concentration,</p> <p>7 dilution, manufacturer, positive controls,</p> <p>8 negative controls. Each day everything is</p> <p>9 recorded.</p> <p>10 Q. Okay. And is it the S100 protein that</p> <p>11 the stain is specifically staining for?</p> <p>12 A. That antibody?</p> <p>13 Q. Yes.</p> <p>14 A. That antibody specific. Because see,</p> <p>15 sometimes what happens in the mouse, you have</p> <p>16 multiple antibodies. So the new step in this</p> <p>17 technology, which I didn't try to draw, is that</p> <p>18 you develop a tumor, neoplastic cells, which</p> <p>19 pump out antibodies, and that becomes</p> <p>20 monoclonal. So you don't have a bunch of</p> <p>21 antibodies including S100, you have just S100.</p> <p>22 So this is again specifically S100.</p> <p>23 Q. Okay. The S100 stain, you tell me all</p> <p>24 the different tissues where that can potentially</p> <p>25 stain positive for. I know you mentioned</p>

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<p>1 nerves.</p> <p>2 A. Schwann cells contain S100,</p> <p>3 melanocytes, adipose tissue, fat, chondrocytes.</p> <p>4 Q. Monocytes, did you mention monocytes?</p> <p>5 A. No. Chondrocytes.</p> <p>6 Q. Chondrocytes.</p> <p>7 A. Can be nonspecific in other cells at</p> <p>8 low levels. The art of pathology is not just to</p> <p>9 be as a machine, you see staining or you don't.</p> <p>10 You interpret it by other means. I can see</p> <p>11 nerves without S100 stain by any staining. So</p> <p>12 if morphology fits, pattern of staining fits,</p> <p>13 then I use it as feature. If I see that</p> <p>14 something is not specific, if it's binding to</p> <p>15 nonspecifically to different structures for</p> <p>16 whatever reason, I either repeat the stain or I</p> <p>17 don't -- I ignore the staining altogether.</p> <p>18 Q. Can S100 stain positive for monocytes?</p> <p>19 A. I would have to check on what exactly.</p> <p>20 It potentially can. It's not commonly used to</p> <p>21 identify monocytes. It's not a specific marker</p> <p>22 for macrophages. At least it's not regarded</p> <p>23 like that in diagnostic field.</p> <p>24 Q. As you sit here today, do you know</p> <p>25 whether S100 can stain monocytes?</p>	<p>1 morphologically.</p> <p>2 Q. Do you know if S100 can stain from --</p> <p>3 strike that.</p> <p>4 Do you know if S100 can stain foreign</p> <p>5 body joint cells?</p> <p>6 A. It's the same cell, histiocytes.</p> <p>7 We're talking about the same thing, just</p> <p>8 different names.</p> <p>9 Q. They're a fusion of macrophages</p> <p>10 together, that's why you're saying they're the</p> <p>11 same cell?</p> <p>12 A. Yes.</p> <p>13 Q. But as you sit here today, you don't</p> <p>14 know whether macrophages, whether they're in a</p> <p>15 single cell or fused foreign body giant cell</p> <p>16 status can stain for S100, correct?</p> <p>17 A. No, I don't know. It didn't strike me</p> <p>18 as strongly positive, otherwise I would have</p> <p>19 seen it. There are probably pictures here.</p> <p>20 Like this one, see (indicating)?</p> <p>21 Q. We're going to get to those.</p> <p>22 A. This --</p> <p>23 MR. FABRY: Let him finish his answer,</p> <p>24 please.</p> <p>25 A. There are macrophages. From this</p>
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<p>1 A. I do not. I don't remember. As I</p> <p>2 said, it's not specifically used for monocytes,</p> <p>3 that's why I don't remember.</p> <p>4 Q. Can S100 stain positive in</p> <p>5 histiocytes?</p> <p>6 A. Monocyte, histocyte, the same cell.</p> <p>7 The answer is possibly can. It's not used,</p> <p>8 therefore I don't know. I can check with the</p> <p>9 list and rate of positivity for specific tissues</p> <p>10 the companies supply.</p> <p>11 Q. Do you have a copy of that list and</p> <p>12 rate of S100 staining back at your lab?</p> <p>13 A. That's either in manual for the</p> <p>14 antibody of the supplier. Or another way of</p> <p>15 checking it, to check immuno queries, there are</p> <p>16 websites and different publications.</p> <p>17 Q. Is that something you could easily do?</p> <p>18 A. For monocyte, yes, I can do that. But</p> <p>19 I don't understand the question. Monocyte is a</p> <p>20 cell. Nerve is the largest structure. So</p> <p>21 morphologically they're so different that I</p> <p>22 wouldn't even think about it.</p> <p>23 Q. Okay.</p> <p>24 A. There's no need to separate one from</p> <p>25 the other because they're so different</p>	<p>1 power I don't see any staining, so in this</p> <p>2 particular slide it did not stain.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. What slide are you talking about?</p> <p>5 A. 64. This is Page 64.</p> <p>6 Q. We will come back to that.</p> <p>7 A. For that specific situation, it did</p> <p>8 not stain. And it's just one picture, I just</p> <p>9 flipped the page, it's not that I was looking</p> <p>10 for.</p> <p>11 Q. Do you know, can S100 protein stain in</p> <p>12 tumors?</p> <p>13 A. Yes.</p> <p>14 Q. Certain cells of lymph nodes?</p> <p>15 A. Yes.</p> <p>16 Q. Can S100 stain for epidural Langhorne</p> <p>17 cells? You're the doctor, not me.</p> <p>18 A. It can stain any cell which can</p> <p>19 contain S100 family of proteins. There might</p> <p>20 be -- we might be talking about at least over</p> <p>21 100 different cells, different situations. As I</p> <p>22 said, we interpret this how it looks basically.</p> <p>23 Q. So S100 is not a single protein, it is</p> <p>24 a family of proteins, correct?</p> <p>25 A. Yes.</p>

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<p>1 Q. There can be over 100 different types 2 of cells that could potentially stain for S100? 3 A. Possibly. Don't quote me for 100. 4 Possibly, as I said, at least within ten, there 5 will be different scenarios. 6 And I have to repeat that the 7 interpretation is not based just brown or blue, 8 interpretation is based on morphological 9 features and correlation between positive 10 staining and morphological features. So I 11 decide if it's specific or not. 12 Q. So what you're testifying to is even 13 if something stains brown, you're the one who 14 decides whether or not it's a real finding? 15 A. Yes. Or if the finding which answer 16 the question. It can be real, it can be real 17 S100 in the monocyte if you want, but it's not 18 specific. I'm using it to highlight nerves. If 19 it's highlighting something else, I just ignore 20 it because it's not my question. 21 Q. Is there a specific stain that looks 22 for nerves, the neurovascular system? 23 A. Just nerves, nothing else? So one 24 single stain, neurofilament, neurofilament will 25 stain. But neurofilament is a really thin</p>	<p>1 about the thickness of the cuts of the tissue 2 with the microtome? 3 A. Yes. Electron microscopy is thinner. 4 Q. For the TEM, the electron microscopy, 5 how thick are those cuts? 6 A. I don't remember now. I think it's 7 half an a micron or 1 micron. It's really thin, 8 very thin. It can be thicker. If tissue starts 9 crumbling, then you get thicker, but it's much 10 thinner than histology. 11 Q. I believe you testified for the 12 electron microscopy there's heavy metal 13 staining? 14 A. I think osmium. 15 Q. Can you spell that for us? 16 A. Again, don't quote me, but I think 17 this is -- metal which is used for. I can check 18 for you. I mean it's accepted standardized 19 protocol for electron microscopy. 20 Q. When you were talking about how the 21 histology samples are fixed, you mentioned 22 formalin, correct? 23 A. Yes. 24 Q. Formalin is a fixative for pathology? 25 A. Yes.</p>
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<p>1 structure, it's difficult to see. I've tried 2 it, it's difficult to interpret. I mean it's 3 easy to interpret when you see it, but it's 4 difficult to see on low power. 5 Q. Did you do any neurofilament staining 6 on Mrs. Edwards? 7 A. No. 8 Q. Did you do any neurofilament staining 9 on any of the other TVT-O mesh specimens? 10 A. I don't remember now. I've tried it, 11 but which brand it was, type, I don't remember. 12 Human body, I don't think there is 13 such a thing as strictly specific staining, 14 because we all have the same genome in each 15 cell, and there might be situations when, for 16 whatever reason, specific environment or 17 specific stimuli, the cell starts producing a 18 protein. They're all encoded in each cell. 19 Q. As you sit here today, you don't 20 recall whether you performed any neurofilament 21 staining on any TVT explanted meshes, correct? 22 A. I don't remember. I could have, but I 23 don't remember. 24 Q. You mentioned 4-micron thick cuts for 25 the histology preparation. Are you talking</p>	<p>1 Q. What exactly is formalin beyond it's a 2 fixative for pathology? 3 A. It's a chemical which is caused by 4 proteins. The proteins gets cross-linked. 5 Q. Just S100 proteins, or all proteins? 6 A. All proteins. It prevents from 7 decomposition. Proteins, cross-linked proteins 8 cannot be digested by bacteria or degrade 9 further. 10 Q. Is formalin the same thing as 11 formaldehyde, or are they two different 12 chemicals? 13 A. Formalin is solution of formaldehyde. 14 It's like vodka and -- well, spirit. 15 Q. And for the formalin fixation in 16 pathology, is there a certain ratio that the 17 formaldehyde is supposed to be concentrated in? 18 A. Yes. It's premixed. The laboratories 19 buy it premixed. It's buffered. It's not just 20 concentration, it's also acidity controlled. 21 And this is again quality assurance, quality 22 control systems in the labs. 23 Q. Is formalin regularly used in the 24 pathology lab at your hospital? 25 A. Yes, in all labs. It's a standard</p>

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<p>1 fixative throughout the world.</p> <p>2 Q. And the paraffin, how does that differ</p> <p>3 from the formalin?</p> <p>4 A. Paraffin is paraffin, like a wax.</p> <p>5 Q. So it's not a preservative? It</p> <p>6 doesn't bind with proteins, or does it?</p> <p>7 A. No. It just mechanically holds</p> <p>8 tissue. To cut tissue you need to hold it. So</p> <p>9 it's imbedded in paraffin, and then the knife</p> <p>10 cuts through paraffin and cuts through the</p> <p>11 tissue. Because otherwise, the tissue would</p> <p>12 fold under the knife.</p> <p>13 Q. When the tissue is in the formalin and</p> <p>14 there's the cross-linking of the proteins, does</p> <p>15 that cross-linking continue over time as the</p> <p>16 tissue remains in the formalin?</p> <p>17 A. Yes, to a degree. But the rate is</p> <p>18 different. And for specific proteins, it's a</p> <p>19 little different. It's variable. But yes.</p> <p>20 Q. When you take the tissue out of the</p> <p>21 formalin and you put it into paraffin, do you</p> <p>22 know whether or not the proteins are still</p> <p>23 cross-linked? Assuming you don't take it out of</p> <p>24 the --</p> <p>25 A. We assume that they are cross-linked,</p>	<p>1 is more gentle than formalin?</p> <p>2 A. Yes. I mean, again, gentle is a</p> <p>3 descriptive term.</p> <p>4 Q. Does glutaraldehyde contain</p> <p>5 formaldehyde?</p> <p>6 A. Maybe traces. I don't know exact</p> <p>7 purity of it. It's aldehyde. It's, I guess</p> <p>8 different tail, different length of the tail of</p> <p>9 aldehyde group.</p> <p>10 Q. Do you know, is there a certain brand</p> <p>11 or manufacturer you use glutaraldehyde from?</p> <p>12 A. I can check. We have diagnostic lab.</p> <p>13 I mean everything is coming from accredited</p> <p>14 manufacturers.</p> <p>15 Q. How does the glutaraldehyde work?</p> <p>16 A. I believe it's the same principle. It</p> <p>17 crosslinks proteins, but in a different way.</p> <p>18 But I'm not -- I don't know exact details,</p> <p>19 what's the difference between formalin and</p> <p>20 glutaraldehyde.</p> <p>21 Q. For formalin, do you know whether --</p> <p>22 well, strike that.</p> <p>23 For formalin, you do know that it</p> <p>24 binds proteins?</p> <p>25 A. Crosslinks.</p>
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<p>1 and the staining protocols and antibodies are</p> <p>2 optimized for cross-linking. So before the</p> <p>3 staining is done, each staining requires</p> <p>4 retrieval of the antibody. So what happens, you</p> <p>5 know that it's cross-linked, therefore you have</p> <p>6 to unlink it. So before staining is done,</p> <p>7 there's unlinking process, or antigen retrieval.</p> <p>8 You have to open the sites where the antibody</p> <p>9 can see the tissue. Then it's being opened by</p> <p>10 different links. So the antibody when it's</p> <p>11 produced by manufacturer is optimized for</p> <p>12 formalin fixed paraffin imbedded tissue.</p> <p>13 Q. So what you're saying is like for the</p> <p>14 S100 antibody, it's optimized by the</p> <p>15 manufacturer, that antibody, to be able to work</p> <p>16 in the histologic specimen which has gone from</p> <p>17 formalin to paraffin to cutting?</p> <p>18 A. Yes.</p> <p>19 Q. I believe you mentioned glutaraldehyde</p> <p>20 for the electron microscopy. What is that?</p> <p>21 A. It's a similar fixative but it's more</p> <p>22 gentle, preserves the tails. It's been found</p> <p>23 experimentally that this is the best fixative</p> <p>24 for fine details.</p> <p>25 Q. The glutaraldehyde is a fixative which</p>	<p>1 Q. For formalin, you know it crosslinks</p> <p>2 proteins, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Is that part of your basic pathology</p> <p>5 training?</p> <p>6 A. Yes.</p> <p>7 Q. Have you had any discussions at all</p> <p>8 with Mrs. Edwards' healthcare providers?</p> <p>9 A. No.</p> <p>10 Q. Have you ever talked to Mr. or</p> <p>11 Mrs. Edwards?</p> <p>12 A. No.</p> <p>13 Q. Have you had any written</p> <p>14 correspondence with any of Mrs. Edwards' medical</p> <p>15 providers?</p> <p>16 A. No.</p> <p>17 Q. Have you spoken with anyone other than</p> <p>18 Mrs. Edwards' lawyers about Mrs. Edwards' case?</p> <p>19 A. No.</p> <p>20 Q. Have you spoken with anyone other than</p> <p>21 Mrs. Huskey's lawyers about Mrs. Huskey's case?</p> <p>22 A. No.</p> <p>23 Q. You didn't speak to any of</p> <p>24 Mrs. Huskey's providers?</p> <p>25 A. No.</p>

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<p>1 Q. And you didn't have any written</p> <p>2 conversations with them either; "them" being</p> <p>3 Mrs. Huskey's providers?</p> <p>4 A. No.</p> <p>5 Q. The medical literature that you</p> <p>6 reviewed, that's all contained within your list</p> <p>7 of materials at the back of your report?</p> <p>8 A. Yes. This was most relevant to the</p> <p>9 report, because I reviewed way more during my</p> <p>10 career. I cannot include everything I've read.</p> <p>11 Q. The most important articles are</p> <p>12 included in your materials list, though, to your</p> <p>13 report?</p> <p>14 A. Yes. Things like S100 protein. I</p> <p>15 mean this is a very long list of literature I</p> <p>16 reviewed as part of my career.</p> <p>17 Q. As you sit here today, are there any</p> <p>18 literature that come to mind that you've seen in</p> <p>19 your career that are of particular importance to</p> <p>20 you for your opinions?</p> <p>21 MR. McCONNELL: You mean other than</p> <p>22 what's on the list?</p> <p>23 MR. SNELL: Absolutely, yes.</p> <p>24 A. Do you mean particularly important for</p> <p>25 this report?</p>	<p>1 list, I believe, contains medical records.</p> <p>2 (Whereupon, Iakovlev Exhibit Number 2,</p> <p>3 Rule 26 Expert Report of Dr. Vladimir</p> <p>4 Iakovlev, Number 3, Document titled</p> <p>5 Facts of Data Considered in Forming</p> <p>6 Opinions, and Number 4, Curriculum</p> <p>7 Vitae of Vladimir Iakovlev, were</p> <p>8 marked for identification.)</p> <p>9 BY MR. SNELL:</p> <p>10 Q. Doctor, I'm handing you Exhibit</p> <p>11 Number 2, 3, and 4 to your deposition (handing).</p> <p>12 (Witness reviewing documents.)</p> <p>13 MR. FABRY: Would it be okay if we</p> <p>14 take a real brief break before we dive into the</p> <p>15 report?</p> <p>16 MR. SNELL: Sure.</p> <p>17 MR. FABRY: Thank you.</p> <p>18 (Whereupon, a recess was taken from</p> <p>19 9:33 a.m. to 9:42 a.m.)</p> <p>20 BY MR. SNELL:</p> <p>21 Q. Just go back to one thing. You</p> <p>22 estimate that you spent 22 to 25 hours on the</p> <p>23 Ethicon litigation up until yesterday, correct?</p> <p>24 A. Yes.</p> <p>25 Q. Now, you have Exhibits 2, 3 and 4 in</p>
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<p>1 BY MR. SNELL:</p> <p>2 Q. Particularly important to you in your</p> <p>3 analysis of the Ethicon meshes.</p> <p>4 A. Depends on the question. I mean if</p> <p>5 specific question, then specific literature. I</p> <p>6 mean something -- one article which answers all</p> <p>7 questions? No, there is none. There is one</p> <p>8 article which gives you this piece of</p> <p>9 information, the other one gives you this piece</p> <p>10 of information. I can't say one single most</p> <p>11 important, no, I cannot.</p> <p>12 Q. As you sit here, are there any</p> <p>13 articles that you intend to discuss at trial</p> <p>14 that you haven't disclosed in your list of</p> <p>15 materials?</p> <p>16 A. Unless you ask me specific question,</p> <p>17 then I can -- if it becomes point of argument.</p> <p>18 Q. But as you sit here today --</p> <p>19 A. I don't plan, no.</p> <p>20 Q. All of the medical records and the</p> <p>21 depositions that you reviewed in the Edwards'</p> <p>22 case are listed in your materials list, correct?</p> <p>23 A. Yes. Because, see, when I make</p> <p>24 reference list I make it as for medical</p> <p>25 literature for publication, so I -- reliance</p>	<p>1 front of you?</p> <p>2 A. Yes.</p> <p>3 Q. Exhibit 2 is your expert report,</p> <p>4 correct?</p> <p>5 A. Yes. Yes, it is.</p> <p>6 Q. And Exhibit 3 is the list of facts and</p> <p>7 materials that you rely upon which include</p> <p>8 medical literature, medical records,</p> <p>9 depositions, documents, correct?</p> <p>10 A. Yes. These were made available to me</p> <p>11 by the attorneys.</p> <p>12 Q. Is that an accurate and complete list,</p> <p>13 Exhibit Number 3, of the materials you reviewed?</p> <p>14 A. Well, see, this is -- the point is</p> <p>15 that, as I said, it's whole career, so I've</p> <p>16 reviewed more materials. The list I provided in</p> <p>17 the reference list is what I thought was most</p> <p>18 relevant to this report. I cannot state that</p> <p>19 it's complete, because complete you have to go</p> <p>20 back to articles I read in medical school.</p> <p>21 Q. Are there any articles specifically</p> <p>22 concerning the TVT-O that you're going to rely</p> <p>23 upon and talk about at trial, but which you</p> <p>24 haven't included along with your expert report</p> <p>25 and the list of materials that you provided to</p>

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<p>1 us?</p> <p>2 A. No, I don't think so.</p> <p>3 Q. Okay. Exhibit 4 is your curriculum</p> <p>4 vitae, correct?</p> <p>5 A. Yes.</p> <p>6 Q. I believe you testified that that's</p> <p>7 current? Take a minute and look at it if you</p> <p>8 want to.</p> <p>9 A. There might be a couple of workshops</p> <p>10 happening later, but nothing in terms of major</p> <p>11 publications.</p> <p>12 Q. Any workshops important to your</p> <p>13 opinions in this case?</p> <p>14 A. No.</p> <p>15 Q. I want to go back to Exhibit 1, just</p> <p>16 keeping going through the list of documents, if</p> <p>17 that's okay, Doctor.</p> <p>18 Schedule A, item number seven, do you</p> <p>19 have any documents responsive to item number</p> <p>20 seven?</p> <p>21 A. Which one?</p> <p>22 Q. Number seven.</p> <p>23 A. Number seven, the reference list?</p> <p>24 Q. No. Number 7 to Exhibit Number 1. So</p> <p>25 let's just -- so we're looking at Exhibit</p>	<p>1 records rather than depositions?</p> <p>2 A. Clinical records were more neutral,</p> <p>3 they occurred before the litigation process. I</p> <p>4 believe they're less biased or they have chance</p> <p>5 -- less chance of being biased.</p> <p>6 Q. Exhibit Number 3, take a look at it.</p> <p>7 The facts or data considered, towards the back</p> <p>8 there are some depositions beginning at item</p> <p>9 number 193.</p> <p>10 A. Yes, I see that.</p> <p>11 Q. And the deposition transcripts listed</p> <p>12 here run from 193 to 209.</p> <p>13 A. Yes, I see that.</p> <p>14 Q. You didn't review all of those</p> <p>15 depositions?</p> <p>16 A. No.</p> <p>17 Q. Can you tell me the ones you reviewed?</p> <p>18 A. I don't think I reviewed any of the</p> <p>19 depositions for this litigation.</p> <p>20 Q. Okay. Do you know that there was an</p> <p>21 Ethicon related trial in West Virginia recently</p> <p>22 concerning the TVT?</p> <p>23 A. Yes, I'm aware of that. Just recently</p> <p>24 I was told.</p> <p>25 Q. Who told you?</p>
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<p>1 Number 1, your notice of deposition, Schedule A.</p> <p>2 A. I understand.</p> <p>3 Q. And take a look at number seven. Do</p> <p>4 you have any documents responsive to that</p> <p>5 request?</p> <p>6 A. I wasn't -- work in progress, it's</p> <p>7 privileged, when I communicate with my</p> <p>8 attorneys.</p> <p>9 Q. So then your communications with the</p> <p>10 attorneys, you don't have any other documents</p> <p>11 responsive to number seven?</p> <p>12 A. No.</p> <p>13 Q. Were there any literature, materials,</p> <p>14 documents that were provided to you by the</p> <p>15 attorneys, but you didn't look at it?</p> <p>16 A. There were some deposition records.</p> <p>17 As a pathologist I only screen clinical and</p> <p>18 relevant information for specific features</p> <p>19 relevant to my opinion, so I was selective in</p> <p>20 reviewing records.</p> <p>21 Q. When you say "records," you mean the</p> <p>22 medical records?</p> <p>23 A. Medical records. And I mostly rely on</p> <p>24 clinical records rather than depositions.</p> <p>25 Q. Why do you mostly rely on the clinical</p>	<p>1 A. An attorney. My attorney.</p> <p>2 Q. Your personal attorney?</p> <p>3 A. No.</p> <p>4 Q. The gentlemen sitting here today?</p> <p>5 A. Yes.</p> <p>6 Q. Do you know the result of that trial?</p> <p>7 A. No.</p> <p>8 Q. Have you read any transcripts from</p> <p>9 that trial?</p> <p>10 A. No.</p> <p>11 Q. Have you had any discussions with any</p> <p>12 expert -- strike that.</p> <p>13 Have you had any discussions with any</p> <p>14 other Plaintiffs' expert in the Ethicon mesh</p> <p>15 litigation?</p> <p>16 A. No.</p> <p>17 Q. Have you had any written</p> <p>18 correspondence with any of the Plaintiffs'</p> <p>19 experts in the Ethicon pelvic mesh litigation?</p> <p>20 A. Specifically for Ethicon, no.</p> <p>21 Q. Have you had any written</p> <p>22 communications with them whatsoever?</p> <p>23 A. If they are experts for this trial and</p> <p>24 I have collaborative projects, research</p> <p>25 projects, yes, we had communication regarding</p>

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<p>1 research projects.</p> <p>2 Q. What collaborative research projects</p> <p>3 are you working on with any other Plaintiffs'</p> <p>4 experts?</p> <p>5 MR. McCONNELL: Are you concerned</p> <p>6 about confidentiality, Doctor?</p> <p>7 THE WITNESS: Yes.</p> <p>8 MR. McCONNELL: Well, are you able to</p> <p>9 list the experts even? Or is that confidential</p> <p>10 as far as you're concerned?</p> <p>11 THE WITNESS: I'm not sure if I can</p> <p>12 give away names and the specific projects,</p> <p>13 because projects are my work in progress, and</p> <p>14 names are names of other people.</p> <p>15 MR. McCONNELL: Okay. Well, if you're</p> <p>16 more comfortable not doing that, I think that's</p> <p>17 your answer.</p> <p>18 MR. SNELL: Well, what's the basis of</p> <p>19 your confidentiality? We're going to have to</p> <p>20 get the judge on the line for this one, because</p> <p>21 this is -- any work he's doing with any other</p> <p>22 Plaintiffs' experts is absolutely discoverable,</p> <p>23 it goes to bias, it goes to all different types</p> <p>24 of things. So we'll figure out how to get the</p> <p>25 judge on the line, because this is nonsense.</p>	<p>1 MR. FABRY: Objection.</p> <p>2 THE WITNESS: -- for different</p> <p>3 litigation process, and now I don't remember who</p> <p>4 is expert for which, and if I tell now that I am</p> <p>5 communicating with such person and he's not in</p> <p>6 this, he's not disclosed as an expert, I just</p> <p>7 don't remember it.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. All right.</p> <p>10 MR. FABRY: Is the collaboration that</p> <p>11 you're doing, is that related to publication, or</p> <p>12 something else?</p> <p>13 THE WITNESS: Publications.</p> <p>14 MR. FABRY: Okay. So all of the</p> <p>15 information that you gave before about concerns,</p> <p>16 prepublication issues, confidentiality related</p> <p>17 to that, is that the concern that we're talking</p> <p>18 about?</p> <p>19 THE WITNESS: Yes.</p> <p>20 MR. FABRY: Okay.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. What research projects are we talking</p> <p>23 about that you are collaborating with other</p> <p>24 experts?</p> <p>25 A. Correlation between histological</p>
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<p>1 BY MR. SNELL:</p> <p>2 Q. What's your basis for believing that</p> <p>3 this is confidential, your work with other</p> <p>4 Plaintiff experts?</p> <p>5 A. Because I will tell you names of other</p> <p>6 people, that's my belief. I don't know if those</p> <p>7 people would object to me disclosing this</p> <p>8 information.</p> <p>9 Q. Well, these names, are these experts</p> <p>10 that have been disclosed by Plaintiffs in the</p> <p>11 litigation?</p> <p>12 A. I have to see a list of experts in</p> <p>13 this specific litigation, because I don't</p> <p>14 remember now who are experts for this</p> <p>15 litigation, who are not.</p> <p>16 MR. FABRY: Are we talking about --</p> <p>17 I'm not trying to interrupt, just get some</p> <p>18 clarification.</p> <p>19 Do you have a hypothetical concern</p> <p>20 that maybe people you're collaborating with</p> <p>21 might also be experts, and you don't even know</p> <p>22 if they're experts?</p> <p>23 THE WITNESS: No, the other way</p> <p>24 around, because they're experts for different</p> <p>25 trials --</p>	<p>1 findings and clinical symptoms, and degradation</p> <p>2 process of polypropylene.</p> <p>3 Q. What are the names of those experts,</p> <p>4 Plaintiffs' experts? I don't care whether</p> <p>5 they're involved in Ethicon litigation or</p> <p>6 another litigation.</p> <p>7 MR. FABRY: I'm just going to raise</p> <p>8 the objection. He's told us that he's concerned</p> <p>9 about prepublication issues and confidentiality</p> <p>10 related to that.</p> <p>11 MR. SNELL: I'm asking for their</p> <p>12 identity. I'm not asking right now for the</p> <p>13 manuscript or whatever the publication is. Do</p> <p>14 you know, Counsel?</p> <p>15 MR. FABRY: No.</p> <p>16 A. If I'm given a list of experts which</p> <p>17 are testifying for this specific trial, I can</p> <p>18 select those which --</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Which ones do you know are Plaintiffs'</p> <p>21 experts in the mesh litigation?</p> <p>22 A. In all mesh litigation --</p> <p>23 Q. Yes.</p> <p>24 A. -- or in specific?</p> <p>25 Q. In all mesh litigation.</p>

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<p>1 A. That's my concern, because I'm giving</p> <p>2 you information I obtained for other litigation</p> <p>3 processes, and I don't know if I can disclose</p> <p>4 that.</p> <p>5 Q. The identity of a person is not</p> <p>6 confidential. I'm not asking you about</p> <p>7 something you communicated with the lawyers</p> <p>8 about.</p> <p>9 I'm asking you for the identity of</p> <p>10 Plaintiffs' experts, who you know are</p> <p>11 Plaintiffs' experts, in a mesh litigation that</p> <p>12 you're working on these collaborative research</p> <p>13 projects with?</p> <p>14 A. In any mesh litigation, or</p> <p>15 specifically TVT?</p> <p>16 Q. Any mesh litigation. Then we can</p> <p>17 drill down and figure out who they are, which</p> <p>18 litigation they are in or whatever.</p> <p>19 MR. McCONNELL: Let me object for a</p> <p>20 second. I think your initial question was in</p> <p>21 the Ethicon litigation, and I think what</p> <p>22 Dr. Iakovlev is saying if you have a list of the</p> <p>23 Plaintiff experts, you could show it to him and</p> <p>24 he could -- this may be a moot question as it</p> <p>25 relates to the Ethicon litigation. And I think</p>	<p>1 be disclosed by participating in this</p> <p>2 litigation, yeah, that's okay with me. But if</p> <p>3 it's another litigation, how can I? I mean then</p> <p>4 I'm telling you that this person is involved in</p> <p>5 some other litigation, maybe he's not okay with</p> <p>6 me telling you this.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. John Steege?</p> <p>9 A. Possible. Again, just give me a list.</p> <p>10 Q. I'm giving you a list.</p> <p>11 John Steege, a physician in North</p> <p>12 Carolina?</p> <p>13 A. So if he's expert, yes, we have -- or</p> <p>14 planning collaborative project.</p> <p>15 Q. Jerry Blaivas, a urologist in New York</p> <p>16 City?</p> <p>17 A. Yes, we are planning collaborative</p> <p>18 project, in stages, but there is nothing yet.</p> <p>19 Q. Bruce Rosenzweig, a physician in</p> <p>20 Chicago, Illinois?</p> <p>21 A. Never heard his name.</p> <p>22 Q. Michael Margolis, a physician in</p> <p>23 California?</p> <p>24 A. Never heard this name.</p> <p>25 Q. Ann Weber?</p>
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<p>1 that might be the first step in this, unless I'm</p> <p>2 wrong.</p> <p>3 A. Because if I now say that, okay, this</p> <p>4 person is an expert for another litigation, then</p> <p>5 I'm disclosing information that he's involved.</p> <p>6 I mean I'm not sure if I can do that.</p> <p>7 MR. FABRY: If we have a non-disclosed</p> <p>8 consulting expert in some litigation, and I'm</p> <p>9 not involved in it and he's not involved in it,</p> <p>10 I do think that's outside the scope of what</p> <p>11 you're entitled to get into here.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. Which of these experts -- give me the</p> <p>14 names of the experts who you know are disclosed</p> <p>15 experts for the Plaintiffs in any mesh</p> <p>16 litigation that you're working with on these</p> <p>17 collaborative research projects.</p> <p>18 MR. FABRY: I'm going to object.</p> <p>19 Asked and answered.</p> <p>20 As he told you, if you give him a list</p> <p>21 he'll look at it and tell you who he recognizes.</p> <p>22 A. I know that you're entitled to know</p> <p>23 the names of experts for this specific</p> <p>24 litigation. I can select it from this list if I</p> <p>25 know that these people actually give consent to</p>	<p>1 A. Never heard this name.</p> <p>2 Q. And what is your involvement with John</p> <p>3 Steege?</p> <p>4 A. We're planning to do a collaboration</p> <p>5 when I take my histological findings, and he --</p> <p>6 and his team takes clinical findings, and we</p> <p>7 check if these are correlating, if any</p> <p>8 histological findings correlates with the</p> <p>9 clinical presentation, and what's the degree of</p> <p>10 correlation.</p> <p>11 Q. How long have you been working with</p> <p>12 Dr. Steege?</p> <p>13 A. As I said, it's just in plans. We</p> <p>14 have not exchanged actual data yet.</p> <p>15 Q. And the project where you and</p> <p>16 Dr. Steege are involved in, what does that</p> <p>17 concern?</p> <p>18 MR. FABRY: Object to the form of the</p> <p>19 question.</p> <p>20 A. Transvaginal devices, transvaginal</p> <p>21 meshes.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. Have you had any written</p> <p>24 communications with Dr. Steege?</p> <p>25 A. Yes, we had e-mails.</p>

19 (Pages 70 to 73)

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<p>1 Q. Have you produced those? Did you</p> <p>2 bring those here today?</p> <p>3 A. No. But it's my privileged</p> <p>4 information, it's research information.</p> <p>5 Q. Have you done any other -- are there</p> <p>6 any writings that concern this project between</p> <p>7 you and Dr. Steege besides the e-mails?</p> <p>8 A. No. As I said, it's only plans, we</p> <p>9 have not exchanged data yet.</p> <p>10 Q. Have you written up a protocol?</p> <p>11 A. No. Again, it was in discussion. We</p> <p>12 haven't reached that stage yet.</p> <p>13 Q. Do you have a mission statement or</p> <p>14 anything that describes the scope of the work</p> <p>15 that you're looking at doing?</p> <p>16 A. No, not yet.</p> <p>17 Q. Who is funding this project between</p> <p>18 you and Dr. Steege?</p> <p>19 A. There is no extra funding needed</p> <p>20 because the histological work is done already,</p> <p>21 as the diagnostic work. And I don't know what's</p> <p>22 involved at his end, but I don't require any</p> <p>23 extra funding.</p> <p>24 Q. Who paid for the histology work?</p> <p>25 A. The samples which came from Steelgate</p>	<p>1 today?</p> <p>2 A. Not from the lab. And as I said,</p> <p>3 myself, I didn't do.</p> <p>4 Q. Do you know who is paying Dr. Steege</p> <p>5 for his work in this collaborative research</p> <p>6 project?</p> <p>7 MS. THOMPSON: Objection.</p> <p>8 MR. FABRY: Objection to form.</p> <p>9 MR. McCONNELL: Objection.</p> <p>10 A. I don't know if he needs any funding.</p> <p>11 There's nothing to do, it's just put all data</p> <p>12 together which is there already in the reports,</p> <p>13 and do simple statistical tests.</p> <p>14 BY MR. SNELL:</p> <p>15 Q. Have statistical tests been done on</p> <p>16 these explanted mesh specimens that you've</p> <p>17 looked at?</p> <p>18 A. Not yet.</p> <p>19 Q. You personally haven't done any</p> <p>20 statistical analyses on any of the explanted</p> <p>21 mesh specimens that you've been involved in?</p> <p>22 A. Yes, I did. But that was before</p> <p>23 Boston -- Ethicon, so it was -- first we started</p> <p>24 with hernia meshes, then we compared hernias to</p> <p>25 scar without the mesh, normal, so done</p>
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<p>1 and other sources of attorneys, the law firms</p> <p>2 paid for the work. Patients which are part of</p> <p>3 St. Michael's system, they were absorbed by</p> <p>4 St. Michael's system. Samples which came from</p> <p>5 other hospitals, they were paid partially by</p> <p>6 insurance companies, partially by referring</p> <p>7 physicians.</p> <p>8 Q. Your histology work for the samples</p> <p>9 that came from Steelgate, the Plaintiffs'</p> <p>10 lawyers paid for that?</p> <p>11 A. Law firms.</p> <p>12 Q. Which law firms?</p> <p>13 A. Motley Rice. Some of it was paid by</p> <p>14 Mueller Law.</p> <p>15 Q. Did you submit invoices to those law</p> <p>16 firms? Strike that.</p> <p>17 Did you or your lab submit invoices to</p> <p>18 those law firms?</p> <p>19 A. Yes, they did. I don't know if all</p> <p>20 Boston Scientific have been invoiced. As I</p> <p>21 said, I have not done my billing yet. My lab</p> <p>22 could have done some initial billing already at</p> <p>23 least for Ms. Edwards because it was early,</p> <p>24 billing had been completed.</p> <p>25 Q. Did you bring any of those bills here</p>	<p>1 statistics with that. That was part of my</p> <p>2 research.</p> <p>3 Q. You haven't done any statistical</p> <p>4 analyses on any of the Ethicon meshes, correct?</p> <p>5 A. No, not yet.</p> <p>6 Q. You haven't done any statistical</p> <p>7 analyses on any of the Ethicon TVT-O meshes,</p> <p>8 correct?</p> <p>9 A. Not specific. I measured some</p> <p>10 parameters. But specifically for correlation</p> <p>11 with clinical symptoms, I mean the correlation</p> <p>12 coefficients and so forth, no. The research</p> <p>13 project is planned to correlate large set of</p> <p>14 data.</p> <p>15 Q. How large of a data set is this</p> <p>16 research project plan to correlate?</p> <p>17 A. Right now I have over 70 transvaginal</p> <p>18 meshes explanted, different manufacturers,</p> <p>19 different designs. Some of them are more</p> <p>20 described; I mean there was more data for some,</p> <p>21 and there is less data for others.</p> <p>22 Q. How do you know what statistical</p> <p>23 analyses you're going to do on this large data</p> <p>24 set?</p> <p>25 A. Well, I mean there are two things you</p>

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<p>1 can do with retrospective data. You can check  2 for correlation between two parameters, or you  3 can check if there is statistical difference  4 between two groups and then you can separate  5 patients by groups, by specific feature,  6 assuming if we -- talking about correlation, I  7 can measure thickness of degradation bark and  8 correlate it with in vivo exposure time, that  9 example of correlation coefficient. Tests  10 between two linear parameters.  11 If we separate them into sort of  12 positive-negative groups, then specific  13 feature -- frequency of specific feature can be  14 measured if it's statistically significant,  15 assuming you separate it by, you see nerves  16 ingrown or not ingrown, so separate two samples  17 and then you measure nerve density, and then you  18 measure statistical significance between nerve  19 density between group where you see ingrown  20 nerves or you don't, because this is  21 positive-negative separation.  22 Q. So you could calculate statistical  23 significance to see whether there's a true  24 statistical difference in nerve density and an  25 area where you see nerves around the mesh versus</p>	<p>1 statistical significance between brands.  2 Q. In your report you list six TVT-O  3 specimens, correct?  4 A. Yes.  5 Q. And that's a small "n," correct?  6 A. That's a small group, yes.  7 Q. And the smaller the "n," the smaller  8 the number of samples one is working with, when  9 you do statistical analyses you have larger  10 confidence intervals?  11 A. Well, the tests will show you, if  12 there is such a huge difference between the  13 groups, six samples will pull it off. I just  14 use specific tests which are accurate and  15 sensitive. I mean there are different tests,  16 parametric, non-parametric. As I said, if it's  17 a big difference, even six samples will show it,  18 if you define that significance is up to  19 95 percent.  20 Q. But as you -- just so we're clear, as  21 you sit here, you haven't done that?  22 A. No.  23 Q. And you haven't determined which  24 particular factors you may look at, correct?  25 A. No, not specifically in a protocol. I</p>
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<p>1 where you see -- versus an area away from the  2 mesh, is that what you're saying?  3 A. What we've done, we took scar tissue  4 from inguinal canal without the mesh, when the  5 hernia was repaired, and then we measured nerve  6 density in the scar within the mesh from the  7 same hernia -- well, from the same type of  8 hernia surgery. And then we took normal tissue  9 which was done -- which was taken before any  10 repairs, and then we compared. So this is  11 example of checking for statistical  12 significance, and see if nerve density gross up,  13 down, then can make a conclusion that mesh  14 either inhibits or promotes nerve proliferation  15 or nerve ingrowth.  16 The protocols need to be designed to  17 answer specific questions. When I collect all  18 data, then there will be several tests  19 performed, depending on questions.  20 Q. So as you sit here today, you haven't  21 statistically analyzed the nerve density for the  22 Ethicon transvaginal mesh explants?  23 A. No. It's a work in progress. I need  24 larger set. And probably I will test if  25 specific brands somehow affect that, if there is</p>	<p>1 can at least view which will probably be in the  2 protocols, a few features.  3 Q. What are those?  4 A. Nerve ingrowth, nerve density,  5 vascular growth, vascular density, amount of  6 scar tissue, amount of inflammation, degree of  7 deformation, thickness of degradation bark,  8 muscle attachment, cause of perforation, nerve  9 atrophy. That's what came to mind in a short  10 list.  11 Q. Okay. How did you come to know  12 Dr. Steege?  13 A. Through the litigation process.  14 Q. Who put you in touch with Dr. Steege?  15 A. Dr. Margaret Thompson. We started  16 discussing this for other litigation sometime in  17 the fall 2013.  18 Q. Dr. Margaret Thompson works with one  19 of the Plaintiffs' law firms, correct?  20 A. Yes.  21 Q. So the Plaintiffs' law firms put you  22 in touch with Dr. Steege, correct?  23 MR. FABRY: Objection. Form,  24 misquotes the testimony.  25 A. Yes, he was -- yes.</p>

21 (Pages 78 to 81)



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<p>1 BY MR. SNELL:</p> <p>2 Q. You didn't know John Steege before the</p> <p>3 Plaintiffs' law firms put you in touch with him,</p> <p>4 correct?</p> <p>5 MR. FABRY: Objection. Form.</p> <p>6 A. No.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. Had you ever met Dr. Steege before you</p> <p>9 began in collaborative research project with</p> <p>10 him?</p> <p>11 MR. FABRY: Objection. Form.</p> <p>12 A. No. I haven't met him actually.</p> <p>13 BY MR. SNELL:</p> <p>14 Q. Did you know Dr. Steege at all before</p> <p>15 you began this collaborative research project</p> <p>16 with him?</p> <p>17 MR. FABRY: Objection. Form.</p> <p>18 A. No.</p> <p>19 BY MR. SNELL:</p> <p>20 Q. You didn't go to school with him,</p> <p>21 correct?</p> <p>22 A. No.</p> <p>23 Q. Didn't do a residency with him,</p> <p>24 correct?</p> <p>25 A. No.</p>	<p>1 Dr. Steege?</p> <p>2 A. Sometime in fall 2013.</p> <p>3 Q. You know Dr. Steege is an expert in</p> <p>4 the Edwards case for the Plaintiffs?</p> <p>5 A. You're telling me. Yes, now I know.</p> <p>6 Q. Your materials list --</p> <p>7 A. Oh, yes, he is, because -- see, my</p> <p>8 concern was that he could have been for</p> <p>9 different litigation.</p> <p>10 Yes, he is.</p> <p>11 Q. You know Dr. Steege is an expert in</p> <p>12 the Huskey case for the Plaintiffs, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you know that because you saw his</p> <p>15 expert report, correct?</p> <p>16 A. Yes.</p> <p>17 Q. When did you first get in touch with</p> <p>18 Dr. Jerry Blaivas?</p> <p>19 A. Sometime -- that was actually this</p> <p>20 year, early this year.</p> <p>21 Q. How did you come to get in touch with</p> <p>22 Dr. Jerry Blaivas?</p> <p>23 A. During litigation process.</p> <p>24 Q. Who put you in touch with Dr. Jerry</p> <p>25 Blaivas, Plaintiffs' expert?</p>
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<p>1 Q. Didn't do a fellowship with</p> <p>2 Dr. Steege, correct?</p> <p>3 A. No.</p> <p>4 Q. You've never done any prior research</p> <p>5 with Dr. Steege before this collaborative</p> <p>6 research project, correct?</p> <p>7 MR. FABRY: Objection. Form.</p> <p>8 A. No.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. You understand Dr. Steege is a paid</p> <p>11 expert for the Plaintiffs in this litigation,</p> <p>12 correct?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Have you personally met Dr. Steege?</p> <p>15 A. No.</p> <p>16 Q. Have you seen him via videoconference?</p> <p>17 A. No, we had only audio conference.</p> <p>18 Q. How many audio conferences have you</p> <p>19 had with Dr. Steege?</p> <p>20 A. Sometimes it's hard to say who is in</p> <p>21 the conference, who is participating. I think</p> <p>22 at least one or two times we had teleconference,</p> <p>23 but it was not specifically for TVT litigation,</p> <p>24 for Ethicon litigation.</p> <p>25 Q. When did you first get in touch with</p>	<p>1 A. Attorneys from Motley Rice.</p> <p>2 Q. Which specific attorney from Motley</p> <p>3 Rice put you in touch with Dr. Jerry Blaivas?</p> <p>4 A. I think it was Dr. Thompson, but I'm</p> <p>5 not sure now. I have to think if it was</p> <p>6 Dr. Thompson.</p> <p>7 Q. What communications have you had with</p> <p>8 Dr. Jerry Blaivas, Plaintiffs' expert, in the</p> <p>9 Edwards and Huskey cases?</p> <p>10 A. We never discussed Huskey and Edwards</p> <p>11 case.</p> <p>12 Q. What communications have you had with</p> <p>13 Dr. Jerry Blaivas?</p> <p>14 A. We had discussions regarding generally</p> <p>15 transvaginal meshes, but we did not discuss this</p> <p>16 patient specifically.</p> <p>17 Q. Before the attorneys from Motley Rice</p> <p>18 put you in contact with Dr. Blaivas, did you</p> <p>19 know him?</p> <p>20 A. No.</p> <p>21 Q. Do you have Dr. Blaivas' contact</p> <p>22 information so that when you want to talk to him</p> <p>23 you can get in touch with him?</p> <p>24 A. Yes, through e-mail.</p> <p>25 Q. And that information was provided by</p>

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<p>1 the Plaintiffs' lawyers?</p> <p>2 MR. FABRY: Objection. Form.</p> <p>3 A. I now don't remember if he e-mailed me</p> <p>4 first or somebody connected. But we have e-mail</p> <p>5 conversation. I met him personally as well.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. You've e-mailed Dr. Blaivas?</p> <p>8 A. Yes.</p> <p>9 Q. All right. Has he e-mailed you?</p> <p>10 A. Yes.</p> <p>11 Q. Have you written to him other than</p> <p>12 e-mails, you know, in a letter, or sent anything</p> <p>13 in writing to him?</p> <p>14 A. No.</p> <p>15 Q. When did you meet Dr. Blaivas?</p> <p>16 A. Sometime early this year.</p> <p>17 Q. And why did you meet with Dr. Blaivas?</p> <p>18 A. Again, to discuss the possible</p> <p>19 collaboration or planned collaboration, because</p> <p>20 he has specific clientele, so he extracts the</p> <p>21 samples, and he has a large experience.</p> <p>22 Q. So you met with Dr. Blaivas to discuss</p> <p>23 the transvaginal meshes?</p> <p>24 A. Yes.</p> <p>25 Q. Do you know Dr. Blaivas is being paid</p>	<p>1 out early morning, and he just landed late</p> <p>2 night, so hotel was right in the airport and we</p> <p>3 agreed to meet.</p> <p>4 Q. How long did that meeting take place</p> <p>5 between Dr. Blaivas and yourself?</p> <p>6 A. An hour, maybe just over an hour.</p> <p>7 Q. What did Dr. Blaivas say to you during</p> <p>8 that hour-long meeting?</p> <p>9 A. We discussed transvaginal meshes, and</p> <p>10 his findings, his experience. And I told him --</p> <p>11 or explained what I see in the pictures.</p> <p>12 Q. Why was Dr. Blaivas in Chicago?</p> <p>13 A. I don't know. He could have been</p> <p>14 meeting somebody from the same law firm. I</p> <p>15 don't know.</p> <p>16 Q. Dr. Rosenzweig is a Plaintiffs' expert</p> <p>17 in this litigation, he's in Chicago. Are you</p> <p>18 certain you've never met him or talked to him?</p> <p>19 A. No.</p> <p>20 Q. You're not certain, or you are</p> <p>21 certain?</p> <p>22 A. Repeat his name?</p> <p>23 Q. Rosenzweig.</p> <p>24 A. I have never seen him.</p> <p>25 Q. Have you heard his name, though, other</p>
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<p>1 as an expert by the Plaintiffs?</p> <p>2 A. Yes.</p> <p>3 Q. Where did this meeting take place?</p> <p>4 A. That was in Chicago.</p> <p>5 Q. Where at in Chicago?</p> <p>6 A. In my hotel room.</p> <p>7 Q. Do you know the date when you were</p> <p>8 staying at this hotel room?</p> <p>9 A. No, I don't remember.</p> <p>10 Q. Who else was there in the hotel room</p> <p>11 besides you and Dr. Blaivas?</p> <p>12 A. Nobody.</p> <p>13 Q. Why were you in Chicago?</p> <p>14 A. I had a deposition there.</p> <p>15 Q. What deposition?</p> <p>16 A. For the litigation, transvaginal</p> <p>17 litigation.</p> <p>18 Q. Which one?</p> <p>19 A. AMS.</p> <p>20 Q. But you didn't meet Dr. Blaivas --</p> <p>21 strike that.</p> <p>22 At what time did you meet Dr. Blaivas?</p> <p>23 A. Oh, it was late at night.</p> <p>24 Q. Late at night?</p> <p>25 A. Yes. We were crossing. I was flying</p>	<p>1 than -- strike that.</p> <p>2 Have you heard his name prior to when</p> <p>3 I raised his name with you?</p> <p>4 A. No.</p> <p>5 Q. Have you had any other meetings with</p> <p>6 Dr. Blaivas?</p> <p>7 A. No.</p> <p>8 Q. This collaborative research project,</p> <p>9 besides Drs. John Steege and Jerry Blaivas, are</p> <p>10 there any other pathologists involved?</p> <p>11 A. I'm the only pathologist in this.</p> <p>12 Q. Are there any material scientists</p> <p>13 involved in this collaborative research project?</p> <p>14 A. These two physicians?</p> <p>15 Q. Yes, in the project that you're</p> <p>16 involved in.</p> <p>17 A. I do have collaborative project with</p> <p>18 material scientists.</p> <p>19 Q. Who are they?</p> <p>20 A. We're going back to the same question.</p> <p>21 I don't know if they are experts. And if they</p> <p>22 are not, then I'm disclosing their names that</p> <p>23 they're involved in this, so I'm not sure if I</p> <p>24 can give away this information.</p> <p>25 Q. Dr. Kleiman?</p>

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<p>1 A. No.</p> <p>2 Q. Anybody from Germany?</p> <p>3 Dr. Klosterhalfen?</p> <p>4 A. No.</p> <p>5 Q. Tomas Mühl, Tomas Mühl?</p> <p>6 A. No.</p> <p>7 Q. Dr. Jordi?</p> <p>8 A. No.</p> <p>9 Q. Dr. Dunn?</p> <p>10 A. Yes. His name is -- you mean from</p> <p>11 Vanderbilt?</p> <p>12 Q. Yes.</p> <p>13 A. Yes, yes, his name is -- he's doing</p> <p>14 one of the testing.</p> <p>15 Q. What test is Dr. Dunn doing?</p> <p>16 A. It's spectral analysis of surface</p> <p>17 polypropylene filaments.</p> <p>18 Q. Who else from Vanderbilt is involved</p> <p>19 in this project besides Dr. Dunn?</p> <p>20 A. Coming back to the same situation. If</p> <p>21 you list the names and you tell me that you're</p> <p>22 entitled to hear the name, I will say yes.</p> <p>23 Q. My position is I'm entitled to know</p> <p>24 all these folks who are Plaintiffs' experts in</p> <p>25 the mesh litigation.</p>	<p>1 MR. FABRY: Well, actually let's be</p> <p>2 real precise. It's a planned possible project.</p> <p>3 And in terms of what's relevant to this</p> <p>4 particular case or cases, going through a list</p> <p>5 of the experts in this case and whether those</p> <p>6 folks are involved in the potential project,</p> <p>7 that seems to be a fair and reasonable scope.</p> <p>8 MR. SNELL: Well, I'll keep going.</p> <p>9 But we're going to get all the names eventually.</p> <p>10 So I mean we can spend all day going through the</p> <p>11 names.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. So Dunn from Vanderbilt, how did you</p> <p>14 come to meet Dr. Dunn?</p> <p>15 A. Because he's doing an XPS analysis,</p> <p>16 and when the question became if we converge the</p> <p>17 XPS analysis, we and the doctors did.</p> <p>18 Q. Who put you in touch with Dr. Dunn?</p> <p>19 A. That's the name, I guess, we are stuck</p> <p>20 with, because it's another researcher who is</p> <p>21 doing collaboration with him.</p> <p>22 Q. The Plaintiffs' lawyers were the ones</p> <p>23 who ultimately put you in touch with Dr. Dunn,</p> <p>24 correct?</p> <p>25 A. No. I contacted him through another</p>
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<p>1 A. If it's -- if he's involved in this</p> <p>2 litigation, yes, I can tell. But I need to see</p> <p>3 the list. The same thing, if you list the names</p> <p>4 I'll tell you.</p> <p>5 Q. You know in your head who these</p> <p>6 Plaintiffs' experts are, correct?</p> <p>7 MR. McCONNELL: Wait a minute. We've</p> <p>8 already gone through the routine. If you're</p> <p>9 going to list a name, he'll say yes or no.</p> <p>10 MR. SNELL: We are wasting time --</p> <p>11 MR. McCONNELL: No, we're not.</p> <p>12 MR. SNELL: -- me having to go through</p> <p>13 and extract this stuff like I'm at a dentist</p> <p>14 office.</p> <p>15 MR. McCONNELL: We're being very</p> <p>16 precise, and he's protecting privileges of</p> <p>17 potential confidential situations with other</p> <p>18 subjects. If you have a name, you can ask him,</p> <p>19 he'll answer yes or no. That's how it's been</p> <p>20 working.</p> <p>21 MR. SNELL: He's testified that</p> <p>22 Plaintiffs' experts -- or Plaintiffs' law firms</p> <p>23 are paying him for this collaboration, or at</p> <p>24 least part of it. Are you telling me that</p> <p>25 there's a privileged attached to that?</p>	<p>1 researcher.</p> <p>2 Q. How did you contact Dr. Dunn?</p> <p>3 A. Through another researcher.</p> <p>4 I have to clarify that the project</p> <p>5 with Dr. Blaivas is not actually paid or will</p> <p>6 not be paid by the attorneys, because the plan</p> <p>7 was for future specimens, so specimens he'd</p> <p>8 already done outside of the litigation process.</p> <p>9 And we specifically discussed that this will not</p> <p>10 be covered by either industry or lawyers. And I</p> <p>11 have some funds for this.</p> <p>12 So we cannot apply blanket statement</p> <p>13 that these projects are paid by law firms.</p> <p>14 Q. Do you know how much Dr. Blaivas has</p> <p>15 been paid by Plaintiffs' law firms for the mesh</p> <p>16 litigation?</p> <p>17 A. No. But this exact project was</p> <p>18 designed, or is in discussion to be designed to</p> <p>19 be specifically free of any external funding.</p> <p>20 Q. Is there a protocol that you're</p> <p>21 referencing?</p> <p>22 A. We have not made formal protocol. But</p> <p>23 in the discussion we were talking about</p> <p>24 retrospective and prospective specimens from his</p> <p>25 clientele, and specifically that cost will be</p>

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<p>1 absorbed by either my research funds or his</p> <p>2 research funds.</p> <p>3 Q. Your research funds, how do you gather</p> <p>4 those?</p> <p>5 A. Those specifically, I have like a</p> <p>6 nonspecific fund which was provided by my</p> <p>7 university. Then I can apply for grants.</p> <p>8 Q. Are you going to use meshes that</p> <p>9 you've gathered in the mesh litigation in your</p> <p>10 analyses?</p> <p>11 A. Yes, they are providing statistics.</p> <p>12 Q. Are you going to use meshes from the</p> <p>13 mesh litigation in your analyses for which you</p> <p>14 have been paid money by Plaintiffs' experts?</p> <p>15 MR. McCONNELL: Objection.</p> <p>16 A. Well, I mean I will combine them with</p> <p>17 all available material. And with available</p> <p>18 material, as I said, some of it came within</p> <p>19 litigation process, some of it came as</p> <p>20 St. Michael's patients, some of it came as</p> <p>21 patients of other hospitals outside of the</p> <p>22 litigation process.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Have you ever met Dr. Dunn?</p> <p>25 A. No.</p>	<p>1 Q. When were you put in touch with</p> <p>2 Dr. Guelcher?</p> <p>3 A. Say it again?</p> <p>4 Q. When were you first put in touch with</p> <p>5 Dr. Guelcher?</p> <p>6 A. It was sometime in fall of 2013.</p> <p>7 Q. What's Dr. Guelcher's role in this</p> <p>8 project involving transvaginal meshes?</p> <p>9 A. He analyzes data together with</p> <p>10 Dr. Dunn and interprets it.</p> <p>11 Q. And the transvaginal meshes that</p> <p>12 Dr. Guelcher is involved in analyzing data for,</p> <p>13 some of those are meshes from litigation?</p> <p>14 A. Yes.</p> <p>15 Q. How many -- strike that.</p> <p>16 Have you ever e-mailed Dr. Guelcher?</p> <p>17 A. Yes, we have communication through</p> <p>18 e-mail.</p> <p>19 Q. Have you ever had conference calls</p> <p>20 with Dr. Guelcher?</p> <p>21 A. Yes, we have.</p> <p>22 Q. How many conference calls?</p> <p>23 A. I don't remember. As I said,</p> <p>24 sometimes you don't know who is in the</p> <p>25 conference call. At least one.</p>
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<p>1 Q. Have you e-mailed Dr. Dunn?</p> <p>2 A. He was in the chain of e-mail when we</p> <p>3 were discussing the project.</p> <p>4 Q. Any conference calls with Dr. Dunn?</p> <p>5 A. I don't think so.</p> <p>6 Q. Did you ever have any conference calls</p> <p>7 with Dr. Blaivas?</p> <p>8 A. I don't think so.</p> <p>9 Q. Guelcher?</p> <p>10 A. Yes, that's the --</p> <p>11 Q. That's the other Vanderbilt person,</p> <p>12 right?</p> <p>13 A. Yes.</p> <p>14 Q. That you're involved in in this</p> <p>15 collaborative project, correct?</p> <p>16 A. Yes.</p> <p>17 Q. You understand Guelcher is an expert</p> <p>18 for the Plaintiffs?</p> <p>19 A. Now I do. You told me.</p> <p>20 Q. Who put you in touch with Plaintiffs'</p> <p>21 expert Guelcher?</p> <p>22 A. It was for other litigation process,</p> <p>23 attorneys with Motley Rice.</p> <p>24 Q. Which attorney?</p> <p>25 A. I don't remember.</p>	<p>1 Q. Have you ever met Dr. Guelcher in</p> <p>2 person?</p> <p>3 A. Yes.</p> <p>4 Q. How many times have you met</p> <p>5 Dr. Guelcher?</p> <p>6 A. I believe one time.</p> <p>7 Q. Where did you meet Dr. Guelcher?</p> <p>8 A. He came to my office in Toronto.</p> <p>9 Q. Why was he in Toronto?</p> <p>10 A. We were discussing findings.</p> <p>11 Q. So Dr. Guelcher flew up to your office</p> <p>12 in Toronto to discuss transvaginal mesh</p> <p>13 findings, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Who paid for his plane ticket to get</p> <p>16 to your office in Toronto?</p> <p>17 A. I don't know.</p> <p>18 Q. How long was Dr. Guelcher up in</p> <p>19 Toronto when he came to see you?</p> <p>20 A. Several hours.</p> <p>21 Q. How long did you meet with</p> <p>22 Dr. Guelcher when he came to see you in Toronto</p> <p>23 about transvaginal mesh?</p> <p>24 A. Maybe two hours.</p> <p>25 Q. And you and Dr. Guelcher discussed</p>

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<p>1 transvaginal mesh during that meeting in</p> <p>2 Toronto?</p> <p>3 A. Yes.</p> <p>4 Q. And some of those meshes are from the</p> <p>5 mesh litigation, correct?</p> <p>6 A. Yes, some of them. Yes. But not all</p> <p>7 of them.</p> <p>8 Q. And have you been to Vanderbilt?</p> <p>9 A. No.</p> <p>10 Q. Are you planning to go see</p> <p>11 Dr. Guelcher?</p> <p>12 A. Not at this time.</p> <p>13 Q. Do you have any trips planned to see</p> <p>14 any other Plaintiffs' experts?</p> <p>15 A. Not at this time.</p> <p>16 Q. Do you have any plans to see any</p> <p>17 Plaintiffs' experts while you're here in Boston?</p> <p>18 A. No.</p> <p>19 Q. Are you going to go to New York City</p> <p>20 and see Dr. Blaivas?</p> <p>21 A. Not at this time.</p> <p>22 Q. Before Plaintiffs' lawyers put you in</p> <p>23 touch with Dr. Guelcher, you didn't know him at</p> <p>24 all, correct?</p> <p>25 A. No.</p>	<p>1 Q. In January of this year, 2014?</p> <p>2 A. I believe it was January, yes. It</p> <p>3 wasn't that long ago. It was earliest December,</p> <p>4 late February, sometime within that time frame.</p> <p>5 Q. Which mesh samples did you send to</p> <p>6 Vanderbilt to the other Plaintiffs' experts?</p> <p>7 A. It was not Ethicon.</p> <p>8 Q. Which ones were they?</p> <p>9 A. It was a sling, but not Ethicon.</p> <p>10 Q. Which sling was it?</p> <p>11 A. I don't remember now. I have to see</p> <p>12 the recording which exactly. I remember it was</p> <p>13 a sling.</p> <p>14 Q. You have a record of the sling that</p> <p>15 you did ship to the other Plaintiffs' experts in</p> <p>16 Vanderbilt. As you sit here today, you don't</p> <p>17 recall the type of sling?</p> <p>18 A. Yes.</p> <p>19 Q. Was it a single sling you shipped to</p> <p>20 the other Plaintiffs' experts in Vanderbilt?</p> <p>21 A. It was multiple filaments.</p> <p>22 Q. What do you mean by "multiple</p> <p>23 filaments"?</p> <p>24 A. Filaments were --</p> <p>25 (Phone interruption.)</p>
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<p>1 Q. No, I'm wrong; or yes, I'm correct?</p> <p>2 A. Yes, you're correct, I had not known</p> <p>3 him.</p> <p>4 Q. And Dr. Guelcher is the one who put</p> <p>5 you in touch with Dr. Dunn, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And how did Dr. Guelcher put you in</p> <p>8 touch with Dr. Dunn?</p> <p>9 A. We needed to discuss the protocol, how</p> <p>10 we supply the specimens, and how they are</p> <p>11 processed.</p> <p>12 Q. You just testified "we needed to</p> <p>13 discuss the protocol, how we supply the</p> <p>14 specimens, and how they are processed." What do</p> <p>15 you mean by that?</p> <p>16 A. Because specimens were in my lab, I</p> <p>17 needed to separate them, separate filaments, and</p> <p>18 ship them to Vanderbilt.</p> <p>19 Q. Have you sent anything to Vanderbilt</p> <p>20 regarding the transvaginal mesh litigation?</p> <p>21 A. The samples.</p> <p>22 Q. The mesh samples?</p> <p>23 A. Yes.</p> <p>24 Q. When did you send the mesh samples?</p> <p>25 A. I believe it was early this year.</p>	<p>1 BY MR. SNELL:</p> <p>2 Q. Let me go back because we had an</p> <p>3 interruption.</p> <p>4 What do you mean by multiple filaments</p> <p>5 which were shipped to the Plaintiffs' experts in</p> <p>6 Vanderbilt by you?</p> <p>7 A. The filaments were separated from the</p> <p>8 mesh, so I had to pick under microscope</p> <p>9 filaments which were pulled out of the tissue</p> <p>10 without tissue. Because you need to do analysis</p> <p>11 on the mesh which is free of tissue, have</p> <p>12 exposed surface, so I could do it.</p> <p>13 Q. How did you pick the filaments out of</p> <p>14 the mesh in the tissue?</p> <p>15 A. Use forceps and scalpel.</p> <p>16 Q. Did the other Plaintiffs' experts tell</p> <p>17 you how to pick the filaments out of the</p> <p>18 transvaginal mesh samples?</p> <p>19 A. No.</p> <p>20 Q. Is that something you devised on your</p> <p>21 own?</p> <p>22 A. Yes.</p> <p>23 Q. When you testified you had to work on</p> <p>24 this protocol regarding taking the filaments</p> <p>25 out, what protocol are you talking about?</p>

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<p>1 A. The question is the chemical 2 composition of the surface. So filaments were 3 either from a brand new mesh sling or specimens 4 which are from explanted mesh, and then 5 filaments can also be mechanically scratched to 6 remove the degradation layer. So these are the 7 possibilities to create control samples and test 8 samples. 9 Q. And that's part of what you discussed 10 with the Plaintiffs' experts from Vanderbilt, 11 Dr. Dunn and Guelcher? 12 A. Yes, but the -- I designed the 13 protocol of excision and preparation. 14 Q. Did you bring that protocol with you 15 today? 16 A. No, because it's not for this 17 litigation. I'm still concerned that I'm 18 disclosing this because it was for different -- 19 not within the Ethicon. 20 Q. And this is -- you didn't send any 21 filaments to Drs. Dunn and Guelcher from the 22 Ethicon TVT mesh? 23 A. No. 24 Q. Why not? 25 A. Because I did not have a sample of</p>	<p>1 avoid artifacts of fixation, or you try to avoid 2 measuring chemical composition of the body 3 parts. That's why you need clean filament not 4 exposed to formalin. This provides you the 5 cleanest protocol for the experiment. 6 Q. And do you plan on doing this analysis 7 on the Ethicon TVT meshes? 8 A. No. I don't have a mesh which was 9 excised in this fashion from Ethicon. 10 Q. The multiple filaments that you 11 separated, was that from one mesh or multiple 12 meshes? 13 A. From one mesh. One mesh. 14 Q. Do you know the manufacturer of that 15 mesh as you sit here today? 16 A. No. I think I stated that I don't 17 remember. 18 Q. Where did that mesh come from? 19 A. You mean who supplied the specimen? 20 Q. Yes. 21 A. It was part of litigation process, a 22 litigation process, I don't remember which one, 23 though. 24 Q. Was it sent by Steelgate to you? 25 A. I don't remember that either. Because</p>
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<p>1 Ethicon mesh excised and not exposed to 2 formalin. I had a specific sample which 3 happened to be dry and tissue-free, this is rare 4 occurrence. So if it's not exposed to formalin 5 you avoid artifacts of formalin, if it's pulled 6 out of tissue clean with the tissue you do not 7 clean the filaments, so you avoid artifacts of 8 tissue cleaning, therefore you measure exactly 9 what was in vivo. 10 Q. So if there's been exposure to 11 formalin or -- if there's exposure to formalin, 12 there could be artifacts from that? 13 A. There can be hypothesis that it can 14 create artifacts. 15 Q. You just testified there can be 16 artifacts, correct? 17 A. I did not say that there can be, but 18 possible. I think I testified possible. 19 Q. And there can be artifacts from it 20 when it's exposed to the body? 21 MR. FABRY: Objection to form. 22 BY MR. SNELL: 23 Q. Is that you testified to? 24 A. No. You test if the changes to 25 polypropylene mesh occur in vivo, and you try to</p>	<p>1 I received specimens from at least two 2 depositories, and Mueller Law directly. So 3 there was three sources, at least three sources. 4 Q. So there are at least three sources 5 where you get meshes from -- strike that. 6 There are at least three sources where 7 you get transvaginal meshes which are involved 8 in the litigation; one being Steelgate, correct? 9 A. Yes. 10 Q. One being Mueller's law firm, correct? 11 A. Yes. 12 Q. And the third is what? 13 A. Another depository, it's something 14 Bio, but I don't remember exact name. 15 Q. Do you know where this -- is it a 16 company, Bio? 17 A. It's a company. 18 Q. Are they in Canada, or the United 19 States? 20 A. United States. 21 Q. Where are they at? 22 A. I don't remember. 23 Q. Biosynthesis? 24 A. I don't remember. It was smaller 25 number, maybe five, six samples.</p>

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<p>1 Q. How many samples have you gotten from</p> <p>2 Steelgate?</p> <p>3 A. I can't tell you now. It's at least</p> <p>4 40, 50.</p> <p>5 Q. Do you have a list somewhere of the</p> <p>6 samples you received from Steelgate?</p> <p>7 A. I have a list of samples I have, and</p> <p>8 then there's information where they came from,</p> <p>9 yes.</p> <p>10 Q. Do you have that -- did you bring that</p> <p>11 list today?</p> <p>12 A. No.</p> <p>13 Q. The six TVT-O meshes, where did they</p> <p>14 come from?</p> <p>15 A. I would have to check.</p> <p>16 Q. You don't have any documentation today</p> <p>17 as to where they came from?</p> <p>18 A. No.</p> <p>19 Q. How many meshes did you get from --</p> <p>20 strike that.</p> <p>21 How many of these transvaginal meshes</p> <p>22 involved in litigation did you get from Mueller?</p> <p>23 A. At least one.</p> <p>24 Q. Is that the best you can do?</p> <p>25 A. Ms. Edwards' came from there.</p>	<p>1 St. Michael's for a patient who is involved in</p> <p>2 mesh litigation?</p> <p>3 A. No.</p> <p>4 Q. How did you come to receive this</p> <p>5 sample from St. Michael's then?</p> <p>6 A. It's part of my job. I receive</p> <p>7 specimens from patients. Just one of the</p> <p>8 patients happened to have identified Ethicon</p> <p>9 mesh. I mean there are others, I mean sometimes</p> <p>10 I cannot identify which manufacturer, and it's</p> <p>11 not recorded if it's inserted elsewhere. But</p> <p>12 for this specific, it was identified, and I</p> <p>13 could verify it by blue color.</p> <p>14 Q. What are the five different law firms</p> <p>15 that you receive the TVT-O meshes from?</p> <p>16 A. Repeat the question, please?</p> <p>17 Q. Sure.</p> <p>18 I believe you testified you had gotten</p> <p>19 TVT-O meshes from five different law firms. Is</p> <p>20 that wrong?</p> <p>21 A. No, not five different law firms.</p> <p>22 Q. So you got TVT-O meshes on five</p> <p>23 different Plaintiffs in this litigation</p> <p>24 involving Ethicon TVT meshes?</p> <p>25 A. I examined six excised or explanted</p>
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<p>1 Q. Any others?</p> <p>2 A. From what I recall, I think others</p> <p>3 came from Steelgate. But again, I would have to</p> <p>4 check with my records.</p> <p>5 Q. Your records would document whether</p> <p>6 they came from Mueller, Steelgate, or this other</p> <p>7 company, correct?</p> <p>8 A. Yes. I have chain of custody forms.</p> <p>9 Six samples we are talking about; five from law</p> <p>10 firms, one was St. Michael's Hospital patient.</p> <p>11 So one sample wasn't within litigation process,</p> <p>12 I just received it, and it was identified as</p> <p>13 Ethicon, and I could clearly see blue color of</p> <p>14 the filaments.</p> <p>15 Q. The one from St. Michael's, what</p> <p>16 patient is that? Is that in this litigation?</p> <p>17 A. I analyzed it, so I find features for</p> <p>18 Ethicon.</p> <p>19 MR. FABRY: You're saying it's not</p> <p>20 litigation?</p> <p>21 BY MR. SNELL:</p> <p>22 Q. That's what I'm asking, is it</p> <p>23 litigation. Is the St. Michael's -- strike</p> <p>24 that.</p> <p>25 Is the sample you received from</p>	<p>1 meshes with confirmed Ethicon brand: One of</p> <p>2 this is Plaintiff for this litigation,</p> <p>3 Ms. Edwards; four came from law firms, were sent</p> <p>4 to me; and one was St. Michael's patient.</p> <p>5 Q. And the explant for Mrs. Edwards, that</p> <p>6 came from the Plaintiffs' law firm?</p> <p>7 A. Yes. It came from Mueller Law.</p> <p>8 Q. You have to speak up a little bit just</p> <p>9 so she can hear you.</p> <p>10 A. Mueller Law.</p> <p>11 Q. Kulkarni, K-U-L-K-A-R-N-I, do you know</p> <p>12 a Dr. Kulkarni?</p> <p>13 A. No, I never heard his name.</p> <p>14 Q. David Eberle?</p> <p>15 A. (Nodding in the negative).</p> <p>16 Q. Ron Luke.</p> <p>17 A. I didn't have any contacts with</p> <p>18 anybody else.</p> <p>19 Q. Pandit?</p> <p>20 A. We listed everybody already. I mean</p> <p>21 all other researchers I collaborated were</p> <p>22 outside the litigation process.</p> <p>23 Q. So other than Drs. Steege, Blaivas,</p> <p>24 Dunn, and Guelcher, all the other researchers</p> <p>25 are not experts for the Plaintiffs?</p>

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<p>1 A. No. I stated I collaborated with 2 Dr. Bendavid. 3 Q. You didn't state that. 4 A. In this statement, that's how -- my 5 involvement in the meshes. It's Page 1. 6 Q. You're aware Dr. Bendavid is an expert 7 for the Plaintiffs? 8 A. For this specific? I'm not. I don't 9 know. 10 Q. You're aware Dr. Bendavid is an expert 11 for Plaintiffs in transvaginal mesh litigation? 12 A. For Ethicon litigation, I don't know. 13 Q. I'm not asking for Ethicon litigation. 14 If my question includes something 15 specific to for Ethicon litigation, then that's 16 what I mean. If my question doesn't include 17 that, it's broader. So... 18 A. Then I -- 19 Q. You know, you just told me you know 20 Dr. -- strike that. 21 You know Dr. R. Bendavid is an expert 22 for the Plaintiffs in mesh litigation, correct? 23 MR. McCONNELL: Objection. 24 A. See, I know that he's not -- at least 25 I'm not aware that he's an expert for this</p>	<p>1 Dr. Bendavid was an expert for Plaintiffs in 2 litigation involving hernia meshes? 3 MR. FABRY: Objection. Form, 4 misquotes testimony. 5 A. No. I didn't know about any 6 litigation process until June of 2013. 7 BY MR. SNELL: 8 Q. How did you come to learn about the 9 litigation in June of 2013, as you claim? 10 A. I think it all started with 11 Ms. Edwards. 12 Q. So from sometime in 2012 when you 13 contacted Dr. Bendavid up until June, 2013, you 14 didn't know anything about mesh litigation, is 15 that what you're testifying to? 16 MR. FABRY: Objection. Form, 17 misquotes the testimony. 18 A. Yes. 19 BY MR. SNELL: 20 Q. And how did you come to learn of the 21 mesh litigation in June of 2013? 22 A. I received a specimen from 23 Ms. Edwards, and two other specimens, and then 24 -- I received them from Mueller Law, and then I 25 processed them as routine diagnostic samples as</p>
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<p>1 specific litigation. If I tell you that I know 2 that he is expert for other litigation, then I'm 3 disclosing information which may be confidential 4 to Dr. Bendavid, so we're back to the same 5 question. 6 BY MR. SNELL: 7 Q. Dr. Bendavid is an expert in hernia 8 litigation for the Plaintiffs, correct? 9 A. I don't know. He could have been in 10 the past. I don't know. 11 Q. What is your understanding, who is 12 Dr. Bendavid an expert for? 13 A. He's a surgeon. He contacted me to do 14 research on hernia meshes for research purposes. 15 Q. When did Dr. Bendavid contact you to 16 do this research on hernia meshes? 17 A. 2012. 18 Q. What year? You said -- 19 A. 2012. 20 Q. What month of 2012 did Dr. Bendavid 21 contact you to do research on hernia meshes? 22 A. It was sometime in the second half. I 23 don't remember exact month, but it was close to 24 the end, after summer. 25 Q. You knew at that time that</p>	<p>1 I would examine any other specimen. And they 2 asked me what findings I have. I stated what I 3 have, and it was in my report. And then they 4 said "would you be able to be expert?" 5 Q. Do you know how many cases 6 Dr. Bendavid has looked at for the Plaintiffs in 7 mesh litigation? 8 A. I don't know. 9 Q. Do you know how much he's been paid? 10 A. I don't know. I don't know if he is 11 an expert. 12 Q. Is Dr. Bendavid involved in this 13 collaborative research project with Dr. Blaivas 14 and Steege and Dunn and Guelcher? 15 A. No, because he is in hernia. These 16 specialists are in transvaginal. We may have 17 names on our research papers because some 18 features overlap just to have a broader 19 discussion. 20 Q. What research papers are you 21 discussing or referencing? 22 A. Future, what we can come up with. But 23 he doesn't do anything specifically for these 24 projects, except for maybe writing discussion 25 parts for the papers.</p>

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<p>1 Q. Have you seen the results of any of</p> <p>2 the testing that Drs. Dunn or Guelcher have</p> <p>3 performed on these filaments?</p> <p>4 A. There was a very short communication,</p> <p>5 it was just e-mail, not something formal.</p> <p>6 Q. But do they tell you what their at</p> <p>7 least preliminary analyses were showing</p> <p>8 regarding the filaments you sent them?</p> <p>9 A. Yes. I mean that was the e-mail, they</p> <p>10 measured some traces of this. I didn't go into</p> <p>11 these details.</p> <p>12 Q. Were there any pictures, photographs,</p> <p>13 or diagrams of the spectral analyses done by</p> <p>14 Drs. Dunn and Guelcher in that e-mail?</p> <p>15 A. No.</p> <p>16 Q. When Dr. Ben -- is it your testimony</p> <p>17 that Dr. Bendavid approached you to do work on</p> <p>18 hernia meshes?</p> <p>19 A. Yes.</p> <p>20 Q. And is it your testimony under oath</p> <p>21 that you didn't know that he was an expert for</p> <p>22 Plaintiffs involved in hernia mesh?</p> <p>23 A. Yes, I didn't know.</p> <p>24 Q. So what did he say to you when he</p> <p>25 approached you?</p>	<p>1 A. Yes. When I received the specimens, I</p> <p>2 think I received one for hernia before -- I</p> <p>3 didn't know about the litigation. Then I</p> <p>4 received Ms. Edwards' for transvaginal mesh,</p> <p>5 still didn't know about the litigation. When I</p> <p>6 disclosed my findings to requesting law firms, I</p> <p>7 suspected there might be litigation, but</p> <p>8 formally I didn't know.</p> <p>9 Then I became aware that there is a</p> <p>10 litigation when they asked me to be an expert.</p> <p>11 So this was --</p> <p>12 Q. Well, you got Mrs. Edwards specimen</p> <p>13 from a law firm, correct?</p> <p>14 A. Yes. I suspected it might be for</p> <p>15 litigation, but it could have been just to</p> <p>16 document what -- her planned litigation.</p> <p>17 Because when you receive a specimen from a law</p> <p>18 firm you suspect that there might be some</p> <p>19 litigation. I didn't specifically ask.</p> <p>20 Q. What; did the Mueller firm just send</p> <p>21 you these specimens out of the blue?</p> <p>22 A. I think the contacts were -- I don't</p> <p>23 actually remember how this whole contact. I</p> <p>24 don't remember. Possibly through contacts with</p> <p>25 Dr. Bendavid, then somebody else's contacts.</p>
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<p>1 A. All he said that there is -- there are</p> <p>2 two techniques to repair hernias, which is</p> <p>3 tension repair when you approximate tissue, and</p> <p>4 then there is a mesh when you put a tension-free</p> <p>5 repair. So he believes that surgeons who are</p> <p>6 skillful enough, they can repair hernia without</p> <p>7 mesh. And he sees more complications after</p> <p>8 meshes rather than without the mesh. But he</p> <p>9 didn't understand exactly why it's painful or</p> <p>10 why other changes occur, and he proposed a</p> <p>11 project to look at it under microscope more</p> <p>12 carefully than usually is done.</p> <p>13 Then he supplied samples from patients</p> <p>14 outside of litigation, it wasn't litigation,</p> <p>15 just routine prospectively collected patients</p> <p>16 coming in to Shouldice Hospital. They were sent</p> <p>17 as routine samples, they were processed as</p> <p>18 routine samples.</p> <p>19 Q. Now, I believe you earlier testified</p> <p>20 that you learned of mesh litigation in June of</p> <p>21 2013, correct?</p> <p>22 A. Yes.</p> <p>23 Q. And that's when you received a</p> <p>24 specimen regarding Mrs. Edwards and some others</p> <p>25 from Mueller Law, correct?</p>	<p>1 Q. You know Dr. Bendavid is involved with</p> <p>2 Mueller Law Firm, do you know whether that --</p> <p>3 A. See, if I know or I don't know, then I</p> <p>4 discloses his confidential information. I don't</p> <p>5 know if I can give you. I might be able to give</p> <p>6 you, but then again, I'm concerned about --</p> <p>7 Q. This involves your work in the Ethicon</p> <p>8 litigation. How did you come to get involved in</p> <p>9 the Ethicon litigation?</p> <p>10 MR. FABRY: Objection. Argumentative.</p> <p>11 He's already testified that nothing to</p> <p>12 do with Dr. Bendavid has anything to do with his</p> <p>13 work in the Ethicon litigation.</p> <p>14 MR. SNELL: Actually he didn't say</p> <p>15 that.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. How did Mueller get your name? How</p> <p>18 did Mueller Law Firm get your name?</p> <p>19 A. I don't know. I don't actually know.</p> <p>20 It's through Dr. Bendavid's contact, but who</p> <p>21 specifically gave my name, I don't know. Maybe</p> <p>22 he, maybe somebody else.</p> <p>23 Q. Do you have the letter of when they</p> <p>24 sent these specimens to you?</p> <p>25 A. I have chain of custody with some -- I</p>

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<p>1 mean I had contact with Mueller Law prior to</p> <p>2 Ms. Edwards. There was another specimen for a</p> <p>3 hernia mesh.</p> <p>4 Q. When did you first have contact with</p> <p>5 Mueller Law Firm?</p> <p>6 A. It was just before -- now I don't</p> <p>7 remember if it was Mueller Law. Ethicon came</p> <p>8 from Mueller Law. First sample came as --</p> <p>9 Ms. Edwards' came from Mueller Law. It was all</p> <p>10 through some communication with Dr. Bendavid.</p> <p>11 Q. You were aware that Mueller's Law Firm</p> <p>12 was sending you Mrs. Edwards' mesh before it</p> <p>13 arrived in Toronto in your office, correct?</p> <p>14 A. Yes.</p> <p>15 Q. You were anticipating that the</p> <p>16 Plaintiffs' lawyers were going to send you</p> <p>17 Mrs. Edwards' mesh specimen, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And how was it that you knew that the</p> <p>20 mesh was going to be sent from the Mueller Law</p> <p>21 Firm to you?</p> <p>22 A. I think it was e-mail. I don't</p> <p>23 remember. Could have been phone call, could</p> <p>24 have been e-mail.</p> <p>25 Q. Did you bring here today the</p>	<p>1 Q. Did you bring your Edwards file here</p> <p>2 today?</p> <p>3 A. But you have everything from --</p> <p>4 Q. No, no, no. That's not how it works</p> <p>5 here.</p> <p>6 Did you bring your Edwards file here</p> <p>7 to your deposition today?</p> <p>8 A. No.</p> <p>9 MR. McCONNELL: For the record, I'm</p> <p>10 going to object to "that's not how it works."</p> <p>11 How it works is you ask questions, he answers</p> <p>12 them.</p> <p>13 MR. SNELL: How it works is we asked</p> <p>14 for materials to be brought to the deposition,</p> <p>15 including the Edwards case file, he hasn't</p> <p>16 brought it. I will tell you my experts bring</p> <p>17 their case files to their depositions.</p> <p>18 If you're objecting to him having to</p> <p>19 produce the Edwards case file --</p> <p>20 MR. McCONNELL: I object to extraneous</p> <p>21 comments from you telling us how it work. We</p> <p>22 don't need to hear from you how it works.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Why didn't you bring the Edwards case</p> <p>25 file?</p>
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<p>1 documents, chain of custody, all of those</p> <p>2 materials involving Mrs. Edwards' mesh?</p> <p>3 A. No. But I believe you have chain of</p> <p>4 custody, because I think I sent it.</p> <p>5 Q. Do you have any e-mails about</p> <p>6 Mrs. Edwards' mesh showing what information was</p> <p>7 packaged with the mesh?</p> <p>8 A. I didn't bring it because it was</p> <p>9 exchange of information with lawyers, and again,</p> <p>10 I don't know if it's privileged, if I can</p> <p>11 disclose that.</p> <p>12 Q. Was there a letter, cover letter that</p> <p>13 came with the specimen? Strike that.</p> <p>14 Was there a cover letter that came</p> <p>15 with Mrs. Edwards' specimen?</p> <p>16 A. It was at least chain of custody.</p> <p>17 Then I don't remember what was in the shipment.</p> <p>18 Q. Do you have a file on Mrs. Edwards</p> <p>19 that would have any correspondence from the</p> <p>20 Plaintiffs' law firms transmitting you</p> <p>21 materials?</p> <p>22 A. Yes, I have my report, possible -- I</p> <p>23 usually staple them together -- possible</p> <p>24 previous pathology reports, chain of custody, my</p> <p>25 report, it's all attached together.</p>	<p>1 MR. FABRY: Just want to reiterate the</p> <p>2 objection to --</p> <p>3 A. Because you have everything that was</p> <p>4 in the --</p> <p>5 MR. FABRY: Reiterating the objection</p> <p>6 that the deposition notice with the lengthy list</p> <p>7 of requested items was served allegedly Friday</p> <p>8 and apparently filed Saturday.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. Well, Doctor, we just finalized your</p> <p>11 deposition plans late last week, didn't we?</p> <p>12 A. I don't know when you finalized. What</p> <p>13 do you mean?</p> <p>14 Q. We just finalized the plans to have</p> <p>15 your deposition here in Boston late last week,</p> <p>16 correct?</p> <p>17 A. Apparently.</p> <p>18 Q. You know I was ready to come to</p> <p>19 Toronto tomorrow to depose you?</p> <p>20 MR. FABRY: Objection. Argumentative.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. Do you know that?</p> <p>23 A. Repeat the question.</p> <p>24 Q. Do you know that I was ready to come</p> <p>25 to Toronto tomorrow to depose you --</p>

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<p>1 MR. FABRY: Objection.</p> <p>2 Q. -- at your place?</p> <p>3 MR. FABRY: Relevance and</p> <p>4 argumentative.</p> <p>5 A. I don't know. I was told that the</p> <p>6 deposition is taking place here in Boston</p> <p>7 Monday.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. Why are you here in Boston, besides</p> <p>10 for the deposition?</p> <p>11 A. No, just for the deposition.</p> <p>12 Q. Okay. So you weren't here on prior</p> <p>13 business or meetings?</p> <p>14 A. No.</p> <p>15 Q. And all of your materials are in</p> <p>16 Toronto?</p> <p>17 A. Yes.</p> <p>18 Q. Did you bring the Huskey file here</p> <p>19 today?</p> <p>20 A. I didn't have anything of Huskey. I</p> <p>21 had only clinical records.</p> <p>22 Q. But you didn't bring those today,</p> <p>23 correct?</p> <p>24 A. No. I mean these are listed here.</p> <p>25 Q. Did you look at any explants from</p>	<p>1 meshes when you met with him in Chicago?</p> <p>2 A. No.</p> <p>3 Q. Did Dr. Blaivas tell you about any</p> <p>4 analyses or testing he had done with any meshes</p> <p>5 involved in the transvaginal mesh litigation</p> <p>6 during this meeting in Chicago?</p> <p>7 A. He described his findings, not just</p> <p>8 transvaginal meshes, his other approaches with</p> <p>9 native tissue repair, and overall his</p> <p>10 impression.</p> <p>11 MR. SNELL: Note to request funding</p> <p>12 sources and documentation regarding the project</p> <p>13 between Plaintiffs' experts.</p> <p>14 BY MR. SNELL:</p> <p>15 Q. Is your lab bill to Plaintiffs'</p> <p>16 lawyers separate from your billings?</p> <p>17 A. Yes. They bill their technical fees.</p> <p>18 Q. What are their technical fees?</p> <p>19 A. Accession cases, clerical time, and</p> <p>20 then processing time for technologists, reagent</p> <p>21 use. There are specific fees for each</p> <p>22 procedure.</p> <p>23 Q. Do you have a protocol for how the</p> <p>24 mesh specimens are processed that are involved</p> <p>25 in litigation?</p>
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<p>1 Mrs. Huskey?</p> <p>2 A. No.</p> <p>3 MR. SNELL: Make a note; request to</p> <p>4 produce all e-mails, communications between the</p> <p>5 other Plaintiffs' experts and the doctor, the</p> <p>6 protocol he referenced, his entire Huskey and</p> <p>7 Edwards files as received.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. I'm not sure if I asked you this, but</p> <p>10 when you met with Dr. Blaivas in Chicago, do you</p> <p>11 know why he was in Chicago?</p> <p>12 A. I believe he was meeting someone from</p> <p>13 Motley Rice. But I'm not sure.</p> <p>14 Q. That's --</p> <p>15 A. Maybe he had other business and</p> <p>16 meeting somebody.</p> <p>17 Q. But he told you he was planning on</p> <p>18 meeting someone from Motley Rice?</p> <p>19 A. Either him or somebody else, somebody</p> <p>20 from Motley Rice, that they are meeting him. If</p> <p>21 it was specifically trip to meet someone, I</p> <p>22 don't know, someone in Motley Rice, I don't</p> <p>23 know.</p> <p>24 Q. Did Dr. Blaivas tell you about any</p> <p>25 analyses or testing he had done on any Ethicon</p>	<p>1 A. Not specifically for litigation.</p> <p>2 It's -- as I said, I process them as routine</p> <p>3 diagnostic samples, as I would any other.</p> <p>4 Q. Do you know how much your lab has</p> <p>5 billed Plaintiffs' experts?</p> <p>6 A. No.</p> <p>7 Q. You could get that information if you</p> <p>8 needed to?</p> <p>9 A. Yes.</p> <p>10 MR. SNELL: Note to request that.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. When you send bills for your work as a</p> <p>13 Plaintiffs' expert, who do you send them to?</p> <p>14 A. To my attorney.</p> <p>15 Q. Which attorney would that be?</p> <p>16 A. Motley Rice.</p> <p>17 Q. Who is the attorney at Motley Rice who</p> <p>18 you have had the most contact with?</p> <p>19 A. Dr. Margaret Thompson.</p> <p>20 MR. SNELL: Note to request all</p> <p>21 invoices.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. Number 11 asks for photographs or</p> <p>24 other images including photos of the Plaintiffs</p> <p>25 or products taken by you or for you which relate</p>

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<p>1 to your opinions in this case.</p> <p>2 Now, you have some photographs or</p> <p>3 photomicrographs in your expert report, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And you may have taken others that are</p> <p>6 back at your office?</p> <p>7 A. Yes.</p> <p>8 Q. But you don't have those here today,</p> <p>9 correct?</p> <p>10 A. No.</p> <p>11 MR. SNELL: So request those.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. And those relate to your opinions in</p> <p>14 this case, correct?</p> <p>15 A. Yes.</p> <p>16 MR. McCONNELL: Objection.</p> <p>17 BY MR. SNELL:</p> <p>18 Q. Any graphics, number 12 is any</p> <p>19 graphics or charts prepared by you for use at</p> <p>20 trial.</p> <p>21 A. Repeat the question, please?</p> <p>22 Q. Yes.</p> <p>23 Item number 12 asks for any graphics</p> <p>24 or charts prepared by you for use at trial. Do</p> <p>25 you have any such documents?</p>	<p>1 analyzed?</p> <p>2 A. Yes.</p> <p>3 Q. And the same mesh that's in the</p> <p>4 original TVT is in the TVT-O, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Number 14, Exhibit Number 1, do you</p> <p>7 have any documents that are responsive to item</p> <p>8 number 14?</p> <p>9 A. No. I mean this is a very long list.</p> <p>10 Q. Let's skip to 15, because 15 is more</p> <p>11 specific. I think we can handle 15.</p> <p>12 15 is all specimens, paraffin blocks,</p> <p>13 slides, or other mediums, and all documents</p> <p>14 relating to the approximately 130 explanted mesh</p> <p>15 specimens referenced in your report in this</p> <p>16 case.</p> <p>17 So did you bring those materials to</p> <p>18 the deposition?</p> <p>19 A. No, because some of -- well, all of</p> <p>20 these patients are St. Michael's patient cases,</p> <p>21 because once they enter St. Michael's system it</p> <p>22 becomes St. Michael's case. So they belong to</p> <p>23 St. Michael's, and there is a confidentiality</p> <p>24 behind each specimen.</p> <p>25 What I can produce, I can produce the</p>
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<p>1 A. Oh, no, I don't have anything.</p> <p>2 Q. 13 asks for any Ethicon products in</p> <p>3 your possession.</p> <p>4 Do you have any Ethicon products?</p> <p>5 A. Those I tested, yes, but they are</p> <p>6 opened now.</p> <p>7 Q. Did you bring those Ethicon products</p> <p>8 that you opened and tested?</p> <p>9 A. No.</p> <p>10 Q. Do you still have those Ethicon</p> <p>11 products that you opened and tested?</p> <p>12 A. Yes.</p> <p>13 MR. SNELL: So request to preserve,</p> <p>14 request to produce.</p> <p>15 BY MR. SNELL:</p> <p>16 Q. Please retain those products.</p> <p>17 A. I do, yes. I retain everything.</p> <p>18 Q. And that was a TVT-O sling that you</p> <p>19 tested?</p> <p>20 A. TVT and TVT-O use the same mesh. Yes,</p> <p>21 it was TVT-O.</p> <p>22 Q. Are you looking at Page 33 of your</p> <p>23 report, Doctor?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. That's the TVT-O mesh that you</p>	<p>1 samples where a patient consented for this</p> <p>2 litigation, were those four remaining which I</p> <p>3 received from law firm and other samples, not</p> <p>4 St. Michael's, and not for this litigation</p> <p>5 belong to other litigation processes. So I</p> <p>6 think we are limited to only those which are</p> <p>7 within this litigation because patient consented</p> <p>8 to be exposed and the samples.</p> <p>9 Q. Well, you're relying on 130 explanted</p> <p>10 mesh specimens for your opinions in this case,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And is it your position that I'm</p> <p>14 not -- my client is not entitled to look at that</p> <p>15 same material that you've looked at in the</p> <p>16 formulation of your opinions?</p> <p>17 A. Not in the form of confidential</p> <p>18 information or material which either belongs to</p> <p>19 other litigations or belongs to St. Michael's</p> <p>20 Hospital.</p> <p>21 Q. How many of the 130 explanted mesh</p> <p>22 specimens are involving litigation?</p> <p>23 A. At least 70.</p> <p>24 Q. And you're saying that when those 70</p> <p>25 that involve litigation are sent to you, you put</p>

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<p>1 them into the St. Michael's system?</p> <p>2 A. Yes.</p> <p>3 Q. These aren't referrals from treating</p> <p>4 doctors to you, correct?</p> <p>5 A. No.</p> <p>6 Q. These are Plaintiffs' lawyers who send</p> <p>7 you specimens, or have specimens arranged to be</p> <p>8 sent to you, in which you then put into the</p> <p>9 St. Michael's system, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And none of these Plaintiffs' treating</p> <p>12 doctors sent any of these litigation specimens</p> <p>13 to you for the purpose of rendering any analyses</p> <p>14 on their behalf, correct?</p> <p>15 MR. FABRY: Objection. Form,</p> <p>16 speculation.</p> <p>17 A. You mean directly from patients --</p> <p>18 from treating physician to me?</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Yes.</p> <p>21 A. Some, I believe, came directly -- I</p> <p>22 think they were requested by law firms, but they</p> <p>23 came directly from the treating physicians.</p> <p>24 Q. All right. The law firms, Plaintiffs'</p> <p>25 law firms made the requests in all of these</p>	<p>1 for the litigations, or they're St. Michael's</p> <p>2 Hospital, or other hospitals. As I said, I mean</p> <p>3 since I've been interested, I've been collecting</p> <p>4 information about them, but patients didn't</p> <p>5 consent to participate in litigation process.</p> <p>6 Q. Well, how many of the 70 patients is</p> <p>7 it your understanding that -- strike that.</p> <p>8 It's your understanding that all of</p> <p>9 the patients who are involved in the mesh</p> <p>10 litigation consented to the release of their</p> <p>11 information regarding their explants?</p> <p>12 A. Yes. That's my understanding.</p> <p>13 Q. Look at item number 17. "Any protocol</p> <p>14 you use, have used, or have developed regarding</p> <p>15 the handling, processing, staining, analysis, or</p> <p>16 testing of the approximately 130 explanted mesh</p> <p>17 specimens referenced in your report."</p> <p>18 A. It's a standard -- it's standard</p> <p>19 protocols for my lab.</p> <p>20 Q. Are those in writing?</p> <p>21 A. We have standard operating procedures.</p> <p>22 Q. Standard operating procedures that</p> <p>23 were applied to the 130 explanted mesh</p> <p>24 specimens?</p> <p>25 A. Yes, they apply to any specimen in the</p>
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<p>1 litigation explants, and they were then sent to</p> <p>2 you, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And those are the ones that you put</p> <p>5 into the St. Michael's system?</p> <p>6 A. Yes. All samples which come to</p> <p>7 St. Michael's to me for analysis are being</p> <p>8 entered into St. Michael's system. I cannot</p> <p>9 order a stain, or cannot do anything, unless</p> <p>10 it's entered in the St. Michael's system.</p> <p>11 Q. Including the 70 at least that are</p> <p>12 involved in litigation?</p> <p>13 A. Yes. So each sample comes with</p> <p>14 patient identifier, with date of birth, type of</p> <p>15 procedure, type of mesh, because they come</p> <p>16 directly from -- they're not altered by storage</p> <p>17 facilities, so they come exactly like I would</p> <p>18 receive it from a physician.</p> <p>19 Q. Look at item number 16.</p> <p>20 A. Yes.</p> <p>21 Q. Do you have any materials responsive</p> <p>22 to item number 16?</p> <p>23 A. It's a long list again. But again,</p> <p>24 the same problem, it's paraffin blocks, they</p> <p>25 belong to patients, and the patients are either</p>	<p>1 lab.</p> <p>2 Q. You don't have those standard</p> <p>3 operating procedures today, correct?</p> <p>4 A. No. Large binders.</p> <p>5 Q. Number 18 asks for "Any protocol</p> <p>6 relating to physical materials, or chemical</p> <p>7 analyses, testing, or study in which you</p> <p>8 participated in any capacity regarding the</p> <p>9 approximately 130 explanted mesh specimens</p> <p>10 referenced in your report."</p> <p>11 First of all, is there such a</p> <p>12 protocol? And if so -- first of all, is there</p> <p>13 such a protocol?</p> <p>14 A. The only testing I do is just analyze</p> <p>15 physically by this simple stretching, that's</p> <p>16 what I do, and it's in the report.</p> <p>17 Q. The standardized stretching you</p> <p>18 mentioned is on Page 33 of your expert report?</p> <p>19 A. Yes. Not standard, I didn't say</p> <p>20 standard. I said simple stretch test. I mean</p> <p>21 there is no standard.</p> <p>22 Q. There's no standard that you applied</p> <p>23 for this simple stretch test you performed and</p> <p>24 which is depicted at Page 33 of your expert</p> <p>25 report?</p>

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<p>1 A. No. I recorded what I did, but</p> <p>2 there's no standard protocol.</p> <p>3 Q. What about of the other 129 explanted</p> <p>4 mesh specimens, is there any protocol relating</p> <p>5 to any physical, material, or chemical analyses</p> <p>6 or testing that you participated in?</p> <p>7 A. Those are diagnostic samples. They</p> <p>8 were processed as diagnostic routine.</p> <p>9 But we are talking about different</p> <p>10 things. Those 130 are explanted patient</p> <p>11 samples. Here is new mesh device.</p> <p>12 Q. So for the 130 explanted mesh</p> <p>13 specimens, were you involved in any physical,</p> <p>14 material, or chemical analyses or testing?</p> <p>15 A. Each specimen is being gross, so there</p> <p>16 is gross description, there's consistency, if</p> <p>17 you call it physical. And then it's being</p> <p>18 stained, so to a degree it's a chemical</p> <p>19 analysis, because you have to visualize. And</p> <p>20 then it's pathological examination of each</p> <p>21 sample.</p> <p>22 Q. So the 130 explanted mesh specimens --</p> <p>23 A. I did histological examination, and to</p> <p>24 whatever degree you can say it's chemical</p> <p>25 testing or physical testing.</p>	<p>1 It's part of pathology laboratory, electron</p> <p>2 microscope.</p> <p>3 Q. Is there a particular person or head</p> <p>4 of that part of St. Michael's lab for the</p> <p>5 electron microscopy?</p> <p>6 A. I'm not sure if there is a specific</p> <p>7 position as a head of electron microscopy. We</p> <p>8 have our department head.</p> <p>9 Q. Well, explain to me, how did you make</p> <p>10 the submission of the mesh specimens to be</p> <p>11 analyzed by electron microscopy?</p> <p>12 A. Oh, I just take a piece, put it in</p> <p>13 glutaraldehyde, and give it to technician in</p> <p>14 electron microscopy. It's a part of the same</p> <p>15 lab; here is the unit for chemistry, here's</p> <p>16 histochemistry, it's part of -- we use the lab</p> <p>17 for routine diagnostic work. It's not something</p> <p>18 specifically we do for commercial service, no.</p> <p>19 Q. Who is the technician you gave these</p> <p>20 samples to?</p> <p>21 A. You need her name?</p> <p>22 Q. Yes.</p> <p>23 A. Sandy Cohen, I believe, C-O-H-E-N.</p> <p>24 Q. Does Sandy Cohen look at these images</p> <p>25 under the electron microscope?</p>
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<p>1 Q. You did gross observations, correct?</p> <p>2 A. Yes.</p> <p>3 Q. You did staining, correct?</p> <p>4 A. Yes.</p> <p>5 Q. You did pathological analysis of the</p> <p>6 slides that were made, correct?</p> <p>7 A. Yes.</p> <p>8 Q. You did some electron microscopy,</p> <p>9 correct?</p> <p>10 A. Only to a limited number of samples.</p> <p>11 Q. Any other testing, though, that you</p> <p>12 did?</p> <p>13 A. No.</p> <p>14 Q. Do you know how many samples you did</p> <p>15 electron microscopy on in total out of the 130</p> <p>16 explanted mesh specimens?</p> <p>17 A. I think I submitted for electron</p> <p>18 analysis up to ten samples, but not all of them</p> <p>19 were usable. So it's less than ten, more than</p> <p>20 five, somewhere in that range.</p> <p>21 Q. Who did you submit them to? Strike</p> <p>22 that.</p> <p>23 Who did you submit the mesh specimens</p> <p>24 to for the electron microscopy?</p> <p>25 A. It's in our lab at St. Michael's.</p>	<p>1 A. No. She processes the tissue as the</p> <p>2 technicians do, and she cuts sections, she gives</p> <p>3 me blue sections which are thicker. I select a</p> <p>4 block, request for her to cut thin sections from</p> <p>5 a specific block. Then she prepares a grid.</p> <p>6 Then she calls me when the grid is ready, and</p> <p>7 she operates the electron microscope. I point</p> <p>8 where she needs to go and where she needs to</p> <p>9 take pictures, and then I interpret these</p> <p>10 pictures.</p> <p>11 Q. You said you submitted up to ten mesh</p> <p>12 specimens for the electron microscopy, but not</p> <p>13 all of them turned out usable?</p> <p>14 A. Yes.</p> <p>15 Q. What do you mean by that, "not all of</p> <p>16 them turned out usable"?</p> <p>17 A. Sometimes you don't get the filament</p> <p>18 in the section because it's a very small piece,</p> <p>19 it's pretty much one-by-one millimeter piece.</p> <p>20 Sometimes you get a filament, sometimes you</p> <p>21 don't. My interest is in filaments. If there's</p> <p>22 no filament, I don't examine. Then some samples</p> <p>23 for some reasons didn't cut well, they were</p> <p>24 crushing, and tissue was burning by the electron</p> <p>25 beam, so I cannot examine them.</p>

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<p>1 Q. The electron beam can burn tissue?</p> <p>2 A. Yes. Plastic, imbedded plastic,</p> <p>3 mainly imbedded plastic. Plastic deforms, and</p> <p>4 you cannot take a picture.</p> <p>5 Q. You said --</p> <p>6 A. The techniques how you avoid that, you</p> <p>7 start warming it up from edges.</p> <p>8 Q. The plastic can burn under the</p> <p>9 electron microscope?</p> <p>10 A. It melts, softens.</p> <p>11 Q. When you said Sandy prepares the grid,</p> <p>12 what do you mean by that?</p> <p>13 A. See, the electron microscope is</p> <p>14 different than regular microscope. So electron</p> <p>15 beam, and for electron beam you need very small</p> <p>16 sections, it's practically one-by-one millimeter</p> <p>17 section. So this tissue which is about one</p> <p>18 micrometer, thicker, I don't remember exactly,</p> <p>19 you cannot put it on anything, it has to be</p> <p>20 hanging in the air. So there is a specific</p> <p>21 copper grill, sort of round grill with bars like</p> <p>22 this supporting the tissue. So the tissue is</p> <p>23 being placed freely on this grid, and then you</p> <p>24 look through holes, you look through the tissue</p> <p>25 within the holes.</p>	<p>1 communications relating to any publications,</p> <p>2 proposed publications, or draft submissions for</p> <p>3 publication authored by you relating to pelvic</p> <p>4 mesh, pelvic organ prolapse, or stress urinary</p> <p>5 incontinence."</p> <p>6 Do you have any such documents?</p> <p>7 A. No. If I had them published I would</p> <p>8 have disclosed them. But since they're not</p> <p>9 published, I have concerns, and I think it's</p> <p>10 privileged.</p> <p>11 Q. What's your reason for -- strike that.</p> <p>12 So you do have documents or</p> <p>13 communications relating to these publications,</p> <p>14 but you haven't brought them here today,</p> <p>15 correct?</p> <p>16 A. Well, the drafts, we work on drafts.</p> <p>17 Q. But you didn't bring the drafts here</p> <p>18 today, correct?</p> <p>19 A. No.</p> <p>20 Q. And these are drafts that involve</p> <p>21 other Plaintiffs' experts like Dr. Steege,</p> <p>22 Blaivas, Guelcher, or Dunn?</p> <p>23 A. Not all. I have publications and</p> <p>24 drafts outside of this group. One involves</p> <p>25 Dr. Guelcher, but not all.</p>
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<p>1 Q. So the electrons pass through the</p> <p>2 copper into the tissue, and that's what you see,</p> <p>3 or is it down?</p> <p>4 A. They don't pass through the copper.</p> <p>5 They pass through the tissue in the holes of the</p> <p>6 grid.</p> <p>7 Q. Okay.</p> <p>8 A. So it looks like this (indicating).</p> <p>9 If you magnify it, so the tissue is here, and</p> <p>10 you can see square holes, and this is copper,</p> <p>11 then you just examine tissue in the hole.</p> <p>12 Q. Okay. You have records back at your</p> <p>13 lab showing which specimens were not ultimately</p> <p>14 usable?</p> <p>15 A. Yes, it can be retrieved. But these</p> <p>16 samples were from different litigation process,</p> <p>17 and some of them were from St. Michael's</p> <p>18 patients. So...</p> <p>19 Q. How many of them are TVT-O meshes?</p> <p>20 A. One, and it was St. Michael's patient.</p> <p>21 One was usable, and you have pictures in the</p> <p>22 report of it.</p> <p>23 Q. That wasn't Mrs. Edwards, correct?</p> <p>24 A. This wasn't Mrs. Edwards.</p> <p>25 Q. Number 20, "All documents or</p>	<p>1 Q. Do you have any other publications</p> <p>2 involving these topics?</p> <p>3 MR. FABRY: Objection to form.</p> <p>4 BY MR. SNELL:</p> <p>5 Q. Strike that.</p> <p>6 Do you have any other drafts of</p> <p>7 publications involving the topics identified in</p> <p>8 number 20?</p> <p>9 A. Again, nothing accepted and published.</p> <p>10 And the drafts, I have only drafts.</p> <p>11 Q. And you didn't bring those because you</p> <p>12 believe they're somehow confidential or</p> <p>13 privileged?</p> <p>14 A. Privileged, yes.</p> <p>15 Q. Did you talk to any of the -- are</p> <p>16 these drafts that have been submitted to a</p> <p>17 journal?</p> <p>18 A. Well, we discussed pre-submission</p> <p>19 inquiries.</p> <p>20 Q. So this is the same thing we discussed</p> <p>21 earlier?</p> <p>22 A. Yes.</p> <p>23 Q. The pre-submission inquiries?</p> <p>24 A. Yes.</p> <p>25 Q. Have you had discussions with any of</p>

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<p>1 the journal editors about whether or not you can</p> <p>2 release these in this litigation?</p> <p>3 A. No.</p> <p>4 Q. Number 22, "Any letters, brochures,</p> <p>5 promotions, or other documents which you</p> <p>6 advertise or discuss your work or availability</p> <p>7 as an expert or consultant."</p> <p>8 A. No, because I'm not an expert in terms</p> <p>9 of I don't make living by working as an expert.</p> <p>10 Q. Do you advertise your services as an</p> <p>11 expert?</p> <p>12 A. No.</p> <p>13 Q. 23, "Copies of the syllabus and texts</p> <p>14 used in any teaching setting by you."</p> <p>15 A. That's very broad. If I go back to my</p> <p>16 medical school, I started teaching my younger</p> <p>17 students, that dates back to late '80s. Do you</p> <p>18 want me to bring all of that?</p> <p>19 Q. Are you currently teaching any</p> <p>20 students in any medical school?</p> <p>21 A. Yes. I'm an academic physician.</p> <p>22 Q. What's your -- are you an associate</p> <p>23 professor?</p> <p>24 A. Assistant. Hopefully I will become</p> <p>25 associate soon.</p>	<p>1 lectures more, sort of broad lectures to medical</p> <p>2 students in Winnipeg, now here I'm more involved</p> <p>3 in this case-based learning.</p> <p>4 Q. Is there a formal textbook in this</p> <p>5 case-based learning?</p> <p>6 A. There are recommended textbooks for</p> <p>7 students.</p> <p>8 Q. Do you know what those are?</p> <p>9 A. One of them is a bible, Robbins,</p> <p>10 usually called Robbins. There's another one by</p> <p>11 Anderson, first author. And usually Facultative</p> <p>12 Medicine compiles a list of recommended</p> <p>13 literature, if they use that specific book or</p> <p>14 another one.</p> <p>15 Q. Robbins text in pathology is the basic</p> <p>16 text you were referring to?</p> <p>17 A. Yes, it's very basic. There are two</p> <p>18 versions of it; one is for medical students, one</p> <p>19 is for residents. There's not just only one, I</p> <p>20 mean there are so many books in pathology.</p> <p>21 Q. Do you teach the postgraduate</p> <p>22 residents?</p> <p>23 A. Yes.</p> <p>24 Q. What course do you teach them?</p> <p>25 A. Anatomical pathology.</p>
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<p>1 Q. What classes do you currently teach?</p> <p>2 A. We have undergraduate medical</p> <p>3 students, we teach pathology course. We have</p> <p>4 postgraduate residents, so we teach them. I</p> <p>5 also give lectures to physiotherapists, there's</p> <p>6 a course for physiotherapists. And I teach</p> <p>7 pathologists at the conference, I conduct</p> <p>8 workshops.</p> <p>9 Q. The pathology; do you teach pathology</p> <p>10 to undergraduate students?</p> <p>11 A. Yes.</p> <p>12 Q. What course is that?</p> <p>13 A. Pathology.</p> <p>14 Q. Just basic pathology, Pathology 101?</p> <p>15 A. It's pathology sort of in relation</p> <p>16 with clinical symptoms. It's mostly</p> <p>17 problem-based learning, like scenario, somebody</p> <p>18 comes with cough, and then we solve into what</p> <p>19 pathology is behind it, and what the</p> <p>20 implications, what we may see under the</p> <p>21 microscope, and then what correlates with</p> <p>22 clinical symptoms.</p> <p>23 Q. Sort of like case analyses in</p> <p>24 pathology?</p> <p>25 A. Yes, it's part of it. I used to give</p>	<p>1 Q. Are there any recommended texts that</p> <p>2 you suggest to them, the postgraduate residents,</p> <p>3 for the anatomic pathology?</p> <p>4 A. They need to use textbooks, broad</p> <p>5 anatomical pathology textbooks. They need to</p> <p>6 use books written for specific subspecialties.</p> <p>7 They need to do literature search. We evaluate</p> <p>8 them for ability to absorb all of that, and</p> <p>9 independently find sources of reliable</p> <p>10 information, and then we teach them how to judge</p> <p>11 if the information is reliable.</p> <p>12 Q. Do you recommend, is Robbins Pathology</p> <p>13 recommended to the postgraduate residents?</p> <p>14 A. Only in the first year.</p> <p>15 Q. Any other texts by name that you</p> <p>16 recall as you sit here today?</p> <p>17 A. Yeah. I mean Sternberg is one good</p> <p>18 book which compiles pretty much all of</p> <p>19 anatomical pathology, or most of it.</p> <p>20 There are some other books. Rosai is</p> <p>21 a bible.</p> <p>22 Q. How do you spell that?</p> <p>23 A. Rosai?</p> <p>24 Q. Yes.</p> <p>25 A. R-O-S-A-I.</p>

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<p>1 And then there's a long list of</p> <p>2 smaller subspecialties. Like if we go to</p> <p>3 gynecological track, it will be Blaustein. If</p> <p>4 we go to urogynecological track, it will be</p> <p>5 Amine. It's a long list. Depends on how narrow</p> <p>6 you want to go. If you want to go for specific</p> <p>7 disease, then it might be just one single book.</p> <p>8 There's no list of recommended</p> <p>9 literature for postgraduate students or</p> <p>10 pathologists overall. We need to decide what is</p> <p>11 reliable. We do use some guidelines when it</p> <p>12 goes to specific questions of billing, eligible</p> <p>13 to bill, or standard of practice in a specific</p> <p>14 geographic area.</p> <p>15 Q. Is Robboy one of the gynecologic</p> <p>16 pathology tests, R-O-B-B-O-Y?</p> <p>17 A. Can you spell it again.</p> <p>18 Q. R-O-B-B-O-Y.</p> <p>19 A. No. At least not that I'm aware of.</p> <p>20 Q. You said you teach pathology at a</p> <p>21 conference. What conference would that be?</p> <p>22 A. It was one in Canadian Association of</p> <p>23 Pathology annual meeting. Another one,</p> <p>24 Pathology Update organized by University of</p> <p>25 Charlton.</p>	<p>1 provided and that you considered in forming your</p> <p>2 opinions."</p> <p>3 Is that -- we've discussed that, too?</p> <p>4 That's materials on your materials list?</p> <p>5 A. Yes.</p> <p>6 Q. Did they -- did the Plaintiffs'</p> <p>7 lawyers give you any other specific information</p> <p>8 about the Edwards or Huskey cases?</p> <p>9 A. Just clinical records. I requested</p> <p>10 clinical records, and I was given clinical</p> <p>11 records.</p> <p>12 Q. "Assumptions that Plaintiffs' counsel</p> <p>13 provided you and that you relied on."</p> <p>14 Were any assumptions provided that you</p> <p>15 relied upon?</p> <p>16 A. No.</p> <p>17 Q. We can set that aside.</p> <p>18 MR. SNELL: Why don't we take a break.</p> <p>19 (Whereupon, a recess was taken from</p> <p>20 11:44 a.m. to 11:58 a.m.)</p> <p>21 BY MR. SNELL:</p> <p>22 Q. We're back on the record.</p> <p>23 Can you tell me the total hours you've</p> <p>24 spent as an expert in any of the -- strike that.</p> <p>25 Can you tell me the total number of</p>
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<p>1 Q. Have you ever given any testimony or</p> <p>2 statements to the US Food &amp; Drug Administration?</p> <p>3 A. No.</p> <p>4 Q. Have you ever given any statements or</p> <p>5 testimony to any U.S. Government investigation?</p> <p>6 A. No.</p> <p>7 Q. Sorry, U.S. Government department?</p> <p>8 A. No.</p> <p>9 Q. Have you given any statements or given</p> <p>10 testimony to the Canadian equivalent of the US</p> <p>11 FDA?</p> <p>12 A. No.</p> <p>13 Q. Have you given any public statements</p> <p>14 concerning transvaginal mesh?</p> <p>15 A. No.</p> <p>16 Q. Have you given any press interviews or</p> <p>17 interviews with reporters regarding mesh?</p> <p>18 A. No.</p> <p>19 Q. Look at number 26 to Exhibit 1,</p> <p>20 "Communications between you and counsel for the</p> <p>21 Plaintiffs to the extent such communications (1)</p> <p>22 relate to your compensation."</p> <p>23 So we've already discussed that?</p> <p>24 A. Do not have billing yet.</p> <p>25 Q. "Identify facts or data that you were</p>	<p>1 hours you've spent serving as an expert in the</p> <p>2 mesh litigation?</p> <p>3 A. You mean the number of hours I spent</p> <p>4 to prepare?</p> <p>5 Q. No. I mean the total hours you've</p> <p>6 spent as a Plaintiffs' expert in mesh</p> <p>7 litigation.</p> <p>8 A. That question, which is hard to</p> <p>9 answer. I can tell you how much time I spent</p> <p>10 for specific report or for number of samples I</p> <p>11 examined. I can estimate.</p> <p>12 So if I said about 70 samples, and it</p> <p>13 takes about one to two hours on average, maybe</p> <p>14 one and a half hours, so 70 times 1.5, so it's</p> <p>15 105, then I prepare the reports, so it can go up</p> <p>16 to 130 hours, somewhere in that ball park.</p> <p>17 Q. Would that include reviewing</p> <p>18 literature and case-specific materials as well,</p> <p>19 or is that additional?</p> <p>20 A. Case-specific material, clinical</p> <p>21 records, yes. Literature I cannot separate. I</p> <p>22 read literature for meshes, for my research.</p> <p>23 Q. The literature you identified in your</p> <p>24 deposition, Exhibit Number 3 --</p> <p>25 A. I have it in here.</p>

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<p>1 Q. -- that's literature you read in 2 connection with your work as a Plaintiffs' 3 expert, correct? 4 A. More of what this is here in Exhibit 5 Number 1, reference list. This was more 6 available, this is, yes. 7 Q. So the literature listed at the back 8 of Exhibit Number 1 is literature you read in 9 connection with your role as a Plaintiffs' 10 expert, correct? 11 A. No. I read this literature either in 12 connection with litigation or as my interest in 13 mesh research. But those documents influence my 14 opinions. 15 Q. Were they important to your opinions? 16 MR. FABRY: Objection. Form. 17 A. To a degree. Maybe I didn't use some 18 articles, but they provided small amount of 19 information which can make a conclusion when you 20 have several articles stating the same thing. 21 So there's no specific article I'm relying on, 22 but more a set of articles. 23 BY MR. SNELL: 24 Q. You did your medical school in Russia? 25 A. Yes.</p>	<p>1 Q. What school did you -- what school did 2 you interview for when you went to Omaha? 3 A. It must be University of Nebraska. 4 I'm -- now it's my guess pretty much, I don't 5 know exact name. 6 Q. Do you know the type of program that 7 you were interviewing for in Omaha? 8 A. It was family practice. 9 Q. Was this also in 2000? 10 A. Yeah, it's all the same. 11 Q. Have you ever practiced medicine in 12 the United States? 13 A. No. 14 Q. Are you a gynecologic pathologist? 15 A. I am a pathologist, anatomical 16 pathologist. So there is no specific 17 certification for gynecological pathologist. 18 You can limit your practice to gynecological 19 pathology, but there is no board certification 20 for gynecological pathology. 21 Q. Did you do a fellowship in gynecologic 22 pathology? 23 A. No. Again, gynecological pathology is 24 not limited to those who do just fellowships. 25 Q. You're an assistant professor of</p>
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<p>1 Q. Were you accepted to a US residency 2 program? 3 A. I had offers. Well, no, I wasn't 4 accepted. I had interviews. 5 Q. Where did you interview in the United 6 States for a residency program? 7 A. I had one interview here at Boston. I 8 had one interview in Omaha. There was a 9 sequence of matches, Canadian match and US 10 match, and if you get matched in one then you 11 automatically be deleted from the other one. So 12 you do interviews all together, but then the 13 system works out the way. So you cannot be 14 accepted to two programs at the same time. 15 Q. When you interviewed in Boston, when 16 was that? 17 A. I believe it was 2000. 18 Q. Was that for a particular school's 19 program? 20 A. Yeah, it was a psychiatry program. 21 Q. Which school? 22 A. I think it was Harvard. 23 Q. You weren't accepted to that program? 24 A. No. As I said, you can only be 25 accepted to only one program.</p>	<p>1 pathology, you've testified? 2 A. Yes. 3 Q. How does one become an assistant 4 professor of pathology at your institution? 5 A. The department of laboratory medicine 6 and pathobiology evaluates your CV, your 7 research profile, and initially you're given 8 rank of lecturer. 9 And then after, I think, that you 10 accumulated enough or contributed enough to the 11 research to the science world, then you apply 12 for promotion. They evaluate your teaching 13 performance, they evaluate your research 14 performance, and the impact of your academic 15 work, and then they either give you or not. 16 Q. So assistant professor of pathology, 17 that's obviously above lecturer? 18 A. Yes. 19 Q. Is that the next step in the promotion 20 process at your facility? 21 A. Yes. 22 Q. What's the highest level at your 23 facility? 24 A. Full professor. 25 Q. Is there such thing as tenure at your</p>

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<p>1 facility in Canada?</p> <p>2 A. There is little bit of difference in</p> <p>3 terminology, but essentially everything follows</p> <p>4 the same steps.</p> <p>5 Lecturer or some equivalent of a</p> <p>6 lecturer; assistant professor, there is no</p> <p>7 equivalent, it's always assistant professor;</p> <p>8 then associate professor; then a full professor.</p> <p>9 Some universities, smaller universities, slower</p> <p>10 sort of profile universities eliminated this</p> <p>11 preliminary altogether, so they just give</p> <p>12 assistant professor right away, or they rename</p> <p>13 this.</p> <p>14 Now, in the United States there are</p> <p>15 different gradations when physicians become</p> <p>16 either fully academic or partial academic, so</p> <p>17 his contribution to academic world is either</p> <p>18 partial -- tenure is pretty much appointment at</p> <p>19 academic institution.</p> <p>20 In Canada, it's usually either you are</p> <p>21 appointed or you are not. So you are in the</p> <p>22 teaching hospital or you are not, you are in the</p> <p>23 community.</p> <p>24 Q. Okay.</p> <p>25 A. It's much sharper distinction.</p>	<p>1 A. Urinary incontinence. It's a sizable</p> <p>2 proportion. Again, I don't know exact number.</p> <p>3 Q. That's fine.</p> <p>4 So your best estimate is out of the 70</p> <p>5 transvaginal meshes, explanted meshes you've</p> <p>6 reviewed, somewhere between 30 and 60 percent</p> <p>7 were slings?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. So if we do the math, that's</p> <p>10 between 21 and 42 of those transvaginal</p> <p>11 explanted meshes are slings?</p> <p>12 A. Yes. Could be higher new.</p> <p>13 Q. And of those 21 to 42 mesh slings, how</p> <p>14 many are from litigation?</p> <p>15 A. The transvaginal meshes, larger</p> <p>16 proportion came as the litigation process,</p> <p>17 smaller proportion came from St. Michael's</p> <p>18 patients. I had to search a few years back to</p> <p>19 collect those.</p> <p>20 Q. So, approximately, would you estimate</p> <p>21 90 percent of the transvaginal explanted mesh</p> <p>22 slings that you've looked at are litigation?</p> <p>23 A. Maybe not as high. Maybe 80 percent.</p> <p>24 But somewhere in that ball park.</p> <p>25 Q. So approximately 80 percent of the</p>
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<p>1 Q. The 130 explanted mesh specimens that</p> <p>2 you have looked at, you note that 60 percent,</p> <p>3 approximately 60 percent are transvaginal,</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And are those the transvaginal mesh</p> <p>7 specimens that you've seen in sum total?</p> <p>8 A. Yes. I mean at the time when I was</p> <p>9 writing this report, these numbers were as</p> <p>10 stated.</p> <p>11 Q. So I believe you testified it was</p> <p>12 approximately 70?</p> <p>13 A. Yes.</p> <p>14 Q. And how many of the 70 are stress</p> <p>15 urinary incontinence meshes versus prolapse</p> <p>16 transvaginal meshes?</p> <p>17 A. I cannot tell you exact number.</p> <p>18 Probably a half. But this can go up to -- from</p> <p>19 30 percent to -- I don't believe it would exceed</p> <p>20 60 percent. So I didn't -- I don't remember</p> <p>21 statistics. It's a sizeable. It's somewhere</p> <p>22 between 30 percent to 60 percent, somewhere in</p> <p>23 there.</p> <p>24 Q. 30 to 60 percent is the urinary</p> <p>25 incontinence?</p>	<p>1 transvaginal mesh slings that are explanted that</p> <p>2 you've looked at are from litigation?</p> <p>3 A. Yes. They were provided by law firms.</p> <p>4 Q. And when these explanted mesh slings</p> <p>5 were provided by the law firms, do you know what</p> <p>6 method of selection they used to come to those</p> <p>7 mesh slings?</p> <p>8 A. When I was requesting them I was</p> <p>9 requesting them to supply all samples.</p> <p>10 Sometimes they would come, they didn't contain</p> <p>11 the mesh, or it was individual curettage, so</p> <p>12 then I was going through them. But my request</p> <p>13 was to supply everything available, just all</p> <p>14 available clinical information, and then I will</p> <p>15 decide what is suitable, what is not.</p> <p>16 Q. Do you have any way of knowing whether</p> <p>17 they provided you with all of the explanted</p> <p>18 meshes?</p> <p>19 A. No.</p> <p>20 Q. Do you know how many cases they</p> <p>21 collected explanted meshes on in total?</p> <p>22 A. No.</p> <p>23 Q. Do you understand there's thousands of</p> <p>24 cases involving the mesh litigation?</p> <p>25 A. Yes, I do understand that. I don't</p>

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<p>1 know what proportion of them contains pathology</p> <p>2 samples, what proportion of those are available</p> <p>3 to me or to other labs, but I do understand that</p> <p>4 there are more than what I've seen.</p> <p>5 Q. And of those 80 percent of mesh slings</p> <p>6 that you've looked at that were provided by the</p> <p>7 law firms, I know you testified that five were</p> <p>8 TVT-O?</p> <p>9 A. Provided -- yes, five.</p> <p>10 Q. And how many of the others -- strike</p> <p>11 that.</p> <p>12 What were the other types of meshes</p> <p>13 that you looked at that were provided by the law</p> <p>14 firms for the slings?</p> <p>15 A. Slings?</p> <p>16 Q. Yes.</p> <p>17 A. They were, as I stated, Boston</p> <p>18 Scientific, AMS, and occasional either all</p> <p>19 manufacturer or unidentified.</p> <p>20 Q. For the TVT-O meshes that you received</p> <p>21 from the law firms, do you know how long those</p> <p>22 meshes were in the body?</p> <p>23 A. I was requesting information, that was</p> <p>24 -- one of my questions was to provide me with</p> <p>25 information of in vivo exposure. Sometimes this</p>	<p>1 approximately the same.</p> <p>2 However, for some patients, like for</p> <p>3 Ms. Huskey, there are no pathology, no</p> <p>4 examination.</p> <p>5 Q. For the TVT mesh specimens, do you</p> <p>6 have information about how long those specimens</p> <p>7 were maintained in formalin before they came to</p> <p>8 you?</p> <p>9 A. Yes. I have dates of excision, and</p> <p>10 then I have dates I performed section.</p> <p>11 Q. That's back at Toronto on your</p> <p>12 computers?</p> <p>13 A. Yes. If we trace back clinical</p> <p>14 records of excision, then my record of pathology</p> <p>15 report.</p> <p>16 Q. On Page 2 of your report at the very</p> <p>17 bottom, you see it says you also had 29</p> <p>18 explanted slings from other brands for analysis?</p> <p>19 A. See, I did have a number.</p> <p>20 Q. So you got 29 other explanted slings</p> <p>21 and six explanted TVT slings?</p> <p>22 A. Yes, at the time of this report.</p> <p>23 Q. Do you know how popular Ethicon's TVT</p> <p>24 mesh is compared to the other explanted sling</p> <p>25 types you looked at?</p>
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<p>1 information was available with clinical records,</p> <p>2 and sometimes it wasn't, depending on the extent</p> <p>3 of clinical records.</p> <p>4 Q. Do you know how the explanted meshes</p> <p>5 were handled following being taken out of the</p> <p>6 body?</p> <p>7 A. Not specifically. I know the</p> <p>8 procedures, surgical procedures of how this is</p> <p>9 done in our hospital, in the hospitals I worked</p> <p>10 at, but I cannot tell you specifically for each</p> <p>11 specimen.</p> <p>12 My understanding is this is done in</p> <p>13 accredited licensed medical institutions, it's</p> <p>14 done more or less uniform fashion.</p> <p>15 We are talking about surgical</p> <p>16 handling?</p> <p>17 Q. Yes.</p> <p>18 A. Yes, that's my answer.</p> <p>19 Q. What about how they were processed and</p> <p>20 handled in the pathology departments?</p> <p>21 A. That's variable, because those</p> <p>22 specimens I received, they come in formalin.</p> <p>23 Again, when they come in formalin, then I assume</p> <p>24 they've been dealt with as accredited</p> <p>25 laboratories, so the protocols should be</p>	<p>1 A. What do you define "popular"?</p> <p>2 Q. How commonly it's used.</p> <p>3 A. No, I don't know. I mean most</p> <p>4 prevalent, as far as I understand, it's a large</p> <p>5 company, so the market share is large.</p> <p>6 Q. Of the 29 others, do any stand out in</p> <p>7 your head as, you know, you having a larger</p> <p>8 volume of that particular mesh type; Monarc, you</p> <p>9 know, by name?</p> <p>10 A. No. It was approximately similar</p> <p>11 ratios, AMS, Boston Scientific. And you can see</p> <p>12 that there were 35, five of them were TVT-O,</p> <p>13 then anywhere between five to ten were other</p> <p>14 manufacturers.</p> <p>15 Q. Do you know what methodology the</p> <p>16 Plaintiffs' lawyers employed when they decided</p> <p>17 which Boston Scientific and AMS meshes to send</p> <p>18 you?</p> <p>19 A. No. As I said, I requested all</p> <p>20 available.</p> <p>21 Q. The bottom of Page 2, you say "This</p> <p>22 randomizes the findings which are common to</p> <p>23 Ethicon and non-Ethicon brands."</p> <p>24 You didn't do a formal randomization</p> <p>25 of these meshes, correct?</p>

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<p>1 A. No.</p> <p>2 Q. No, I'm not correct?</p> <p>3 A. I did not do formal randomization. If</p> <p>4 we talk about randomization as for clinical drug</p> <p>5 trials, no. This term implies that the samples</p> <p>6 came from different sources, from different</p> <p>7 manufacturers, and they were excised in</p> <p>8 different parts of United States, age, spread,</p> <p>9 and everything becomes more sporadic.</p> <p>10 Q. When tissue is taken out of the body</p> <p>11 during surgical excision, isn't it correct that</p> <p>12 it can lose weight?</p> <p>13 A. If it dries? Yes, it can. If water</p> <p>14 dries up, yes, it will become lighter.</p> <p>15 Q. Is that important in -- strike that.</p> <p>16 Does the weight of the tissue, the</p> <p>17 specimen, change depending upon how long is the</p> <p>18 time period between excision and when it's put</p> <p>19 in formalin?</p> <p>20 A. Ask that question again?</p> <p>21 Q. Yes.</p> <p>22 Does change in the weight of the</p> <p>23 explant depend upon how long of a time period</p> <p>24 elapsed between when the explant was excised to</p> <p>25 when it was put in formalin?</p>	<p>1 BY MR. SNELL:</p> <p>2 Q. The published literature that is</p> <p>3 attached to the back of Exhibit Number 2, your</p> <p>4 report, that's literature that the Plaintiffs'</p> <p>5 lawyers provided to you?</p> <p>6 A. No. I mean there might be few items</p> <p>7 which were suggested, but no, they didn't</p> <p>8 provide that to me.</p> <p>9 Q. How do you maintain that literature</p> <p>10 that's identified in the back of the Exhibit</p> <p>11 Number 2, your expert report?</p> <p>12 A. I store some on my hard drive. But</p> <p>13 you cannot store everything, so sometimes I have</p> <p>14 to go back and pull it off-line. It's published</p> <p>15 on-line, and I have access to all this.</p> <p>16 Q. You don't have it printed out in a</p> <p>17 binder anywhere?</p> <p>18 A. Some of it is printed, some of it is</p> <p>19 not.</p> <p>20 Q. You never got binders of literature</p> <p>21 from the Plaintiffs' lawyers?</p> <p>22 A. Not for this litigation. Some</p> <p>23 articles were printed and they showed me this,</p> <p>24 but not everything.</p> <p>25 Q. You've used some literature in the</p>
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<p>1 A. I don't know. We don't measure weight</p> <p>2 at the excision and before we place in formalin.</p> <p>3 I cannot tell you.</p> <p>4 Q. So in the charts or documents that you</p> <p>5 have regarding the litigation mesh slings, you</p> <p>6 don't have any calculations showing weight of</p> <p>7 the specimens?</p> <p>8 A. No. I never measured weight of the</p> <p>9 specimens. We measure weight for specific type</p> <p>10 of specimens to describe a volume of the organ</p> <p>11 when linear dimensions are difficult. For that</p> <p>12 specific purpose, there were no questions which</p> <p>13 can be answered by weight.</p> <p>14 Q. You never measured the molecular</p> <p>15 weight of any of the Ethicon TVT meshes,</p> <p>16 correct?</p> <p>17 A. No.</p> <p>18 Q. Did you measure the molecular weight</p> <p>19 of any of the Ethicon TVT meshes?</p> <p>20 A. I did not measure molecular weight.</p> <p>21 MR. FABRY: You should appreciate how</p> <p>22 to ask good questions.</p> <p>23 MR. SNELL: I'm going to teach him how</p> <p>24 to answer. I understand. It's just the way we</p> <p>25 communicate, different ways, no big deal.</p>	<p>1 different litigations you've been involved in,</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. I take it you did your reports in the</p> <p>5 AMS and Boston Scientific litigation before the</p> <p>6 Ethicon litigation, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Because you were deposed before the</p> <p>9 Ethicon litigation, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And your literature list in those</p> <p>12 reports have similar articles to the ones you're</p> <p>13 citing here?</p> <p>14 A. Yes.</p> <p>15 Q. On Page 3 you talk about how you</p> <p>16 analyze the published literature. And I'm at</p> <p>17 the middle under number 1, "Findings in View of</p> <p>18 Complications," can you tell me your search</p> <p>19 method for that analysis?</p> <p>20 A. For published literature I usually go</p> <p>21 for -- to PubMed website search and enter</p> <p>22 keywords, see what is being available, and use</p> <p>23 different combination of keywords, different</p> <p>24 keywords.</p> <p>25 Q. Do you know what keywords you used?</p>

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<p>1 A. Mesh, vaginal mesh, vaginal slings, 2 sling mesh, degradation. I mean I cannot 3 remember how many times I search, every time I 4 search it was a different. I would exhaust one 5 type of a search and then come up with something 6 else. 7 Q. You talk here about complications or 8 symptoms that can appear de novo or worsen? 9 A. Yes. 10 Q. Did you do any searches about 11 complications and symptoms that actually get 12 better after mesh placement? 13 A. When I was searching for published 14 literature, they were providing all list of 15 complications, and also providing list of 16 parameters they measured to evaluate mesh 17 performance. So they included positive results 18 and their assessment. 19 But since I'm getting excised mesh, by 20 definition somebody excised it for 21 complications, therefore my job is to compare 22 complications with excised specimen, therefore I 23 was limited to that spectrum. 24 Q. You say you've gotten excised mesh for 25 complications. Are you saying that's true for</p>	<p>1 not there's referral sources for Plaintiffs in 2 the transvaginal mesh litigation to go see 3 certain doctors who will explant their mesh? 4 A. No, I don't know. But as I said, to 5 me, clinical part, as far as I understand, the 6 patient can come with symptoms or request them 7 to do something, but then it's up to physician 8 to treat them, and they decide what treatments 9 are best suitable for the patient. 10 Q. Do you know whether or not -- strike 11 that. 12 In your analysis of the transvaginal 13 sling from litigation, do you analyze the time 14 period between when the mesh was put in and when 15 the mesh was taken out to see how commonly, if 16 at all, that Plaintiff reported pain? 17 A. No. But that's interesting question, 18 because it can be correlated if there is enough 19 data, so that's where the collaborative projects 20 are to correlate pain and specifics of the pain 21 with specific findings. 22 Q. You say on Page 4 of your report, I'm 23 under Section 1.1.1.1, "High Nerve Density" -- 24 A. Yes. 25 Q. -- "Descriptions of painful scars are</p>
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<p>1 all of the transvaginal mesh slings? 2 A. True for all excised? 3 Q. Yes. 4 A. If they are excised, they excised them 5 because of complications. 6 Q. How do you know that? 7 A. Why would you excise it without -- if 8 there is no complications? 9 Q. You haven't heard of people, 10 Plaintiffs going to doctors asking for excisions 11 in cases where they're not having symptoms? 12 A. No. I cannot imagine such a scenario. 13 Q. Have you heard of Plaintiffs who go to 14 surgeons asking for mesh to be removed so that 15 they can potentially obtain money? 16 A. No, I have not heard that. 17 Q. You don't know anything about that? 18 A. No. My understanding is patients come 19 with symptoms, clinician evaluates the patients, 20 works up a differential diagnosis, tries 21 non-invasive treatments, and then when the last 22 resort is -- when the differential diagnosis is 23 all narrowed to the mesh, and last resort is 24 excision, they perform excision. 25 Q. Do you know anything about whether or</p>	<p>1 well-known in the literature." 2 Do you see that? 3 A. Yes. 4 Q. What do you mean by that? 5 A. There are published cases when the 6 scar is painful. 7 Q. Is that something you knew when you 8 were working as a surgeon before a pathologist, 9 or is that something you have recently learned 10 as an expert in this litigation? 11 A. Well, I learned as a pathology 12 resident, maybe I had known it before when I was 13 in my medical school, but specifically I 14 remember reading about it as a pathology 15 resident. Because there are specific painful 16 lesions, and you go through differential 17 diagnosis when somebody says painful nodule. So 18 this can be a part of your -- it's a part of 19 your differential diagnosis, just a scar, 20 painful scar, not a neoplastic lesion. 21 Q. So painful scar is something you 22 learned about at the latest by the time of your 23 pathology residency? 24 A. I remember reading about it and paying 25 close attention. I could have learned it</p>

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<p>1 earlier.</p> <p>2 Q. How are scars formed?</p> <p>3 A. Do you want me to start from injury</p> <p>4 until --</p> <p>5 Q. Sure.</p> <p>6 A. So first there is injury to tissues.</p> <p>7 So if tissue is either mechanically damaged or</p> <p>8 chemically or -- so there's physical factors</p> <p>9 damaging tissue or chemical factors, or there's</p> <p>10 inflammation, or there is ischemic damage. So</p> <p>11 if the tissue is destroyed in the area, then</p> <p>12 this becomes either a hematoma or a sort of</p> <p>13 cavity or an area with necrotic tissue. Then</p> <p>14 the periphery of the -- this cavity or necrosis</p> <p>15 still has blood supply, so there are nutrients</p> <p>16 and oxygen coming in, then the cells can come to</p> <p>17 the area, inflammatory cells first, first would</p> <p>18 be neutrophils, some macrophages, then the blood</p> <p>19 vessels can ingrow, and then they can deliver</p> <p>20 mesenchymal cells. And then with the blood</p> <p>21 vessels fibroblasts come, start laying collagen.</p> <p>22 So it becomes a granulation tissue rich in small</p> <p>23 capillaries with loose fibrous tissue and</p> <p>24 inflammatory cells within. Time progresses,</p> <p>25 there's more collagen laid down, inflammatory</p>	<p>1 A. Approximately 25 microns.</p> <p>2 Q. Macrophages?</p> <p>3 A. Oh, that's a large spread. They will</p> <p>4 be larger to begin with, and then they can go</p> <p>5 all the way over 100 microns.</p> <p>6 Q. On average are they about 20,</p> <p>7 25 microns?</p> <p>8 A. I would say larger than that.</p> <p>9 Q. What would you say then?</p> <p>10 A. Maybe 50 microns.</p> <p>11 Q. 50?</p> <p>12 A. 50, 5-0. I don't remember exact</p> <p>13 number. They are significantly larger than</p> <p>14 other inflammatory cells.</p> <p>15 Q. The small capillaries that come in</p> <p>16 there as part of the process to provide</p> <p>17 nutrients to the scar --</p> <p>18 A. Yes.</p> <p>19 Q. -- how large are those, the diameter?</p> <p>20 A. So the smallest capillary will be as</p> <p>21 small as one red blood cell.</p> <p>22 Q. So about seven microns, or nine?</p> <p>23 A. Pretty much close to that. So all</p> <p>24 vessels finally taper down to this, unless it's</p> <p>25 a shunt between arteries and veins.</p>
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<p>1 cells remove debris or whatever. And if it</p> <p>2 cannot remove, then they localize it, and other</p> <p>3 parts become more fibrotic, and so the scars</p> <p>4 mature so there's less cells, less vessels, more</p> <p>5 collagens, so it becomes harder, and gains</p> <p>6 physical strength. That's --</p> <p>7 Q. And that scar formation process that</p> <p>8 you just outlined in basic form, does that occur</p> <p>9 regardless of whether there's a mesh involved?</p> <p>10 A. Yes. It's a nonspecific process.</p> <p>11 Q. Is it a process you learned about</p> <p>12 during your pathology residency?</p> <p>13 A. No. I learned it when I was a medical</p> <p>14 student.</p> <p>15 Q. You mentioned some inflammatory cells,</p> <p>16 and I think you said neutrophils?</p> <p>17 A. Initially neutrophils, yes.</p> <p>18 Q. They come in early?</p> <p>19 A. They're the first cells which come.</p> <p>20 Q. They're there, what, within a couple</p> <p>21 hours of the injury?</p> <p>22 A. A couple, or four hours.</p> <p>23 Q. How big are neutrophils?</p> <p>24 A. Repeat the question? How big?</p> <p>25 Q. Yes. How large are neutrophils?</p>	<p>1 Q. And the fibroblasts that come in, what</p> <p>2 size are they?</p> <p>3 A. Lengthwise or widthwise?</p> <p>4 Q. Tell me both.</p> <p>5 A. Length-wise it can be again pretty</p> <p>6 large, as macrophages over 100 microns.</p> <p>7 Widthwise, it might be 20 microns, somewhere in</p> <p>8 that range. Again I don't know exact number,</p> <p>9 don't remember exact numbers, but these are</p> <p>10 approximations.</p> <p>11 Q. The inflammatory cells, they can</p> <p>12 actually change shape?</p> <p>13 A. Yes.</p> <p>14 Q. I think you have a photograph in here.</p> <p>15 We'll get to it later.</p> <p>16 And that's one of the ways that they</p> <p>17 can deal with something like bacteria, to try to</p> <p>18 get at a bacteria and contain it by changing</p> <p>19 shape so that it can get to a location where</p> <p>20 bacteria is?</p> <p>21 A. Yes.</p> <p>22 Q. They also can set out part of</p> <p>23 themselves called a pseudopodia?</p> <p>24 A. Pseudopodia.</p> <p>25 Q. And that's -- can you describe what a</p>

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<p>1 pseudopodia is from a macrophage?</p> <p>2 A. It's a finger-like projection of a</p> <p>3 cytoplasm. So the cell, from round, it becomes</p> <p>4 like this.</p> <p>5 Q. You say right below that on Page 4</p> <p>6 "The presence of the mesh does not significantly</p> <p>7 affect nerve density in the scar tissue"?</p> <p>8 A. Yes. That was our project with</p> <p>9 Dr. Bendavid, that was our conclusion.</p> <p>10 Q. Have you published on that project</p> <p>11 with Dr. Bendavid?</p> <p>12 A. Manuscript is in preparation. Paper</p> <p>13 has not been accepted yet.</p> <p>14 Q. Have there been any presentations of</p> <p>15 that data with you, Dr. Bendavid, at any</p> <p>16 conferences or meetings?</p> <p>17 A. Not yet.</p> <p>18 Q. Have they been discussed at your</p> <p>19 hospital in the department of pathology or any</p> <p>20 other groups?</p> <p>21 A. Well, I discussed it with Dr. Bendavid</p> <p>22 at my hospital.</p> <p>23 Q. What stage is the manuscript in?</p> <p>24 A. It's almost done.</p> <p>25 Q. You obviously have a copy of that on</p>	<p>1 and non-parametric tests.</p> <p>2 Q. Do you know if any corrections were</p> <p>3 made to the data based on multiple comparisons?</p> <p>4 A. We are going into sort of different</p> <p>5 areas of statistics. This is -- this was a</p> <p>6 simple test, ten virgin tissue, ten scar without</p> <p>7 mesh, and ten mesh specimens. So essentially</p> <p>8 you have to measure, or calculate p-value of the</p> <p>9 difference between these two groups.</p> <p>10 Q. All right. There are multiple</p> <p>11 comparisons in what you just identified?</p> <p>12 A. We -- I think multiple comparisons</p> <p>13 might be a specific statistical term. I don't</p> <p>14 want to mix this. This was a simple two group</p> <p>15 analysis, and then difference between three</p> <p>16 groups.</p> <p>17 Q. Have you calculated the statistical</p> <p>18 significance, if any, affecting nerve density in</p> <p>19 scar tissue concerning mesh slings?</p> <p>20 A. No.</p> <p>21 Q. The statistician that you consulted,</p> <p>22 is that statistician in the -- strike that.</p> <p>23 Is the statistician who you referenced</p> <p>24 going to be named in the manuscript?</p> <p>25 A. Yes.</p>
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<p>1 your computer?</p> <p>2 A. Yes.</p> <p>3 Q. And the mesh you were looking at</p> <p>4 there, was that in the hernia mesh or abdominal</p> <p>5 wall?</p> <p>6 A. Hernia meshes, yes.</p> <p>7 Q. And when you say "The presence of the</p> <p>8 mesh does not significantly affect nerve density</p> <p>9 in the scar tissue," did someone do statistical</p> <p>10 significance calculations to come to that</p> <p>11 conclusion?</p> <p>12 A. Yes.</p> <p>13 Q. Did you do that, or do you have a</p> <p>14 statistician involved?</p> <p>15 A. Well, first initially I do a sort of</p> <p>16 quirk and dirty test, and then when we need</p> <p>17 final to details, a statistician does it.</p> <p>18 Q. Do you know what type of test the</p> <p>19 statistician does to determine statistical</p> <p>20 significance concerning nerve density in the</p> <p>21 scar tissue?</p> <p>22 A. She did non-parametric analysis.</p> <p>23 Q. Do you know the specific test name?</p> <p>24 A. It was a p-value. I don't remember</p> <p>25 exactly now, but there are several parametric</p>	<p>1 Q. And is that statistician somebody at</p> <p>2 your hospital?</p> <p>3 A. She's U of T staff.</p> <p>4 Q. University of Toronto?</p> <p>5 A. Yes.</p> <p>6 Q. Page 4, Section 1.1.1.2, "Ingrowth,"</p> <p>7 you say "The association of nerve entrapment</p> <p>8 with pain is well established in medicine and</p> <p>9 became common knowledge."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And then you say "Since the dawn of</p> <p>13 surgery, surgical techniques have been developed</p> <p>14 to avoid nerve damage and entrapment."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. When did the association of nerve</p> <p>18 entrapment with pain become common knowledge, in</p> <p>19 your opinion?</p> <p>20 A. It's hard to trace now, but you have</p> <p>21 to think that's the effect of it. So once</p> <p>22 people realize that toothache is when the nerve</p> <p>23 is compressed in the root canal, that's where it</p> <p>24 can be traced.</p> <p>25 Q. When did you acquire the knowledge</p>

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<p>1 that nerve entrapment can lead to pain?</p> <p>2 A. In medical school.</p> <p>3 Q. Is that something you were taught</p> <p>4 during basic pathology course in medical school,</p> <p>5 or another course?</p> <p>6 A. Surgery mostly. Yeah, mostly surgery.</p> <p>7 Some neurology.</p> <p>8 Q. Page 4, a little bit further down, you</p> <p>9 say "A knitted polypropylene mesh introduces</p> <p>10 thousands of compartments (pores into the</p> <p>11 body)."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. You're not talking about a TVT mesh</p> <p>15 sling there, correct?</p> <p>16 A. Repeat the question?</p> <p>17 Q. You're not talking about a TVT mesh</p> <p>18 sling, correct?</p> <p>19 A. You're not -- let's phrase it, "A mesh</p> <p>20 of knitted design introduces multiple</p> <p>21 compartments, including TVT Ethicon mesh."</p> <p>22 Q. But you wrote "introduces thousands of</p> <p>23 compartments." And you know the TVT sling is</p> <p>24 only one centimeter wide, correct?</p> <p>25 A. Yes.</p>	<p>1 Q. Okay. And it's your contention that</p> <p>2 there's thousands of pores in that --</p> <p>3 A. Yes.</p> <p>4 Q. -- 15-centimeter piece of mesh tape?</p> <p>5 A. Yes. Now we have to define what's</p> <p>6 support.</p> <p>7 The mesh is needed in the complex</p> <p>8 weave pattern. So the pores are not just those</p> <p>9 which are commonly described in one dimension,</p> <p>10 they're also spaces in third dimension. These</p> <p>11 are also pores. People try to avoid that, but</p> <p>12 it's still there. When you look in the</p> <p>13 microscope you see all this.</p> <p>14 So if you now go to manufacturer</p> <p>15 descriptions of the porosity of the mesh, this</p> <p>16 will be underestimation of the number of</p> <p>17 compartments.</p> <p>18 So this -- if we go to Page 34, the</p> <p>19 convention is that the pores are only on this.</p> <p>20 But that's underestimation, because the space is</p> <p>21 also in third dimension, and these are also</p> <p>22 compartments.</p> <p>23 Q. What brand is that mesh on the left</p> <p>24 that you're pointing to?</p> <p>25 A. Either Ethicon or another brand.</p>
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<p>1 Q. You know how many pores there are per</p> <p>2 centimeter?</p> <p>3 A. I can calculate it. But it's a long</p> <p>4 one.</p> <p>5 Q. Do you know how much tape, on average,</p> <p>6 is left in a woman after she has a TVT-O sling</p> <p>7 put in, the length of tape?</p> <p>8 A. The length of tape, I can go back and</p> <p>9 check the records. I don't remember exactly.</p> <p>10 It's probably up to 10 centimeters or so,</p> <p>11 roughly, my estimate.</p> <p>12 Q. The excess --</p> <p>13 A. More, probably more than 10</p> <p>14 centimeters.</p> <p>15 Q. For TVT-O?</p> <p>16 A. Yes.</p> <p>17 Q. What's your estimate for the length of</p> <p>18 tape?</p> <p>19 A. If you take a length, maybe up to</p> <p>20 15 centimeters.</p> <p>21 Q. You understand that the excess tape is</p> <p>22 cut?</p> <p>23 A. Yes.</p> <p>24 Q. And then the incisions are closed?</p> <p>25 A. Yes.</p>	<p>1 They're all done the same way.</p> <p>2 Q. Those two aren't done the same way.</p> <p>3 If you look at them, they certainly don't look</p> <p>4 the same?</p> <p>5 A. One is blue, one is transparent, but</p> <p>6 the knitting pattern is the same.</p> <p>7 Q. How do you know that?</p> <p>8 A. I can see it.</p> <p>9 Q. What type of mesh is this on the left?</p> <p>10 A. It's a transvaginal sling.</p> <p>11 Q. I'm saying who is the manufacturer?</p> <p>12 What's the type of sling?</p> <p>13 A. I don't remember now.</p> <p>14 Q. Do you have information back at your</p> <p>15 office that identifies, for example, Figure 17a</p> <p>16 in the left, that's a photograph of this type of</p> <p>17 sling?</p> <p>18 A. Yes, it's most likely AMS sling. So</p> <p>19 when the mesh is knitted, the parameters which</p> <p>20 were described as porous is these holes, but</p> <p>21 this is not all the compartments. This is also</p> <p>22 a pore, it's a different dimension, nobody</p> <p>23 looked at it. But when I look in the</p> <p>24 microscope, this compartment is also inhabited</p> <p>25 by living tissue with vessels and nerves, and</p>

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<p>1 they're completely ignored during manufacturing</p> <p>2 description. So if you measure so many pores in</p> <p>3 one centimeter width, you also have to count</p> <p>4 these pores.</p> <p>5 Q. And it's your testimony that there's</p> <p>6 tissue that gets into those pores in Figure 17b,</p> <p>7 the lower right?</p> <p>8 A. Yes.</p> <p>9 Q. What's the distance in microns of that</p> <p>10 space where you see tissue?</p> <p>11 A. This space?</p> <p>12 Q. Yes.</p> <p>13 A. It's over a millimeter.</p> <p>14 Q. And for the picture that's at the</p> <p>15 bottom of Figure 17b on the right, what's the</p> <p>16 size of those mesh pores?</p> <p>17 A. Those small ones, over a millimeter.</p> <p>18 Larger than a millimeter.</p> <p>19 Q. The mesh pores in TVT mesh are larger</p> <p>20 than a millimeter?</p> <p>21 A. What do we define as a pore? Space</p> <p>22 limited by filaments? They will go all the way</p> <p>23 from nothing when the filaments touch each other</p> <p>24 to the largest dimension. So it's a range. It</p> <p>25 will start from 1 micron or whatever, no space</p>	<p>1 recurrence. Patient didn't come for --</p> <p>2 complaining of symptoms as complication of the</p> <p>3 mesh placement, but they came because hernia</p> <p>4 recurred. So the mesh was excised for</p> <p>5 recurrence.</p> <p>6 Q. I think -- I don't think that we --</p> <p>7 you didn't hear my question, I guess.</p> <p>8 Did you look at any mesh slings,</p> <p>9 transvaginal mesh slings, which were -- strike</p> <p>10 that. I'll just ask it again.</p> <p>11 Did you compare any explanted mesh</p> <p>12 slings that were taken out for reasons other</p> <p>13 than those that you assume were due to</p> <p>14 complications?</p> <p>15 A. I think I answered that.</p> <p>16 Q. I'm not talking about hernia, I'm</p> <p>17 talking about mesh slings.</p> <p>18 A. Even before that.</p> <p>19 Q. Okay. Let me understand then.</p> <p>20 A. You asked me if I examined specimens</p> <p>21 which were excised not for complications, and my</p> <p>22 answer was that I -- my understanding is that</p> <p>23 all meshes are excised to treat complications.</p> <p>24 Q. So for the mesh slings that you looked</p> <p>25 at, all of those you looked at were to people</p>
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<p>1 in-between at all, to -- I don't remember exact</p> <p>2 measurement, but it will be over a millimeter.</p> <p>3 Q. Did you measure the pore size of the</p> <p>4 TVT-O mesh?</p> <p>5 A. At one point, yes, I measured this</p> <p>6 linear dimension. The maximum dimension.</p> <p>7 There's no such thing as pore size. There's</p> <p>8 maximum dimension of a pore. Because these</p> <p>9 pores, when they're looked in three-dimensional</p> <p>10 space, start from zero, and then they extend to</p> <p>11 maximum dimension. Maximum dimension can be</p> <p>12 measured.</p> <p>13 Q. And what was the measurement you</p> <p>14 obtained for the maximum dimension of the pore</p> <p>15 of the TVT-O mesh?</p> <p>16 A. I don't remember now. Over a</p> <p>17 millimeter. From -- usually it's over two</p> <p>18 millimeters, largest dimension, or approaches to</p> <p>19 two millimeters, largest dimension.</p> <p>20 Q. Did you compare any explanted mesh</p> <p>21 slings that were taken out for reasons other</p> <p>22 than those that you assume were because of</p> <p>23 complications?</p> <p>24 A. Recurrence. Hernias can recur, so I</p> <p>25 examined those meshes which were taken out for</p>	<p>1 who had complications, to your understanding?</p> <p>2 A. Yes.</p> <p>3 Q. You didn't have a separate group of</p> <p>4 mesh slings that you analyzed that were not</p> <p>5 taken out for patients with complications and</p> <p>6 you compared those two data sets, correct?</p> <p>7 A. No. Because I don't believe such a</p> <p>8 group exists.</p> <p>9 Q. Let's go to Page 12 of your report.</p> <p>10 What I'd like to do is just go through</p> <p>11 the photographs, photo micrographs you have, and</p> <p>12 ask you questions about them.</p> <p>13 All right. We're looking at Figure 1a</p> <p>14 on Page 12 of your report.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And this is from Mrs. Edwards' TVT-O</p> <p>18 sling, correct?</p> <p>19 A. Yes.</p> <p>20 Q. You did S100 protein staining,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. What's the power of the views we're</p> <p>24 looking at for these photographs in Figure 1a?</p> <p>25 A. See, I was preparing this for just</p>

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<p>1 general public, so it include each objective.  2 Then when I prepare the pictures, I crop them,  3 therefore the initial magnification factor is  4 thrown away just by cropping factors. So  5 technically you cannot firmly state what  6 magnification factor the picture is. I can give  7 you approximately dimensions for reference.  8 Q. Sure.  9 A. The filaments are approximately .2  10 millimeter.  11 Q. Did you measure the filament diameter?  12 A. Yes. Approximately .2-millimeter  13 plus/minus.  14 Q. Plus/minus what?  15 A. Error of measurement. Or maybe they  16 varied, maybe they're not all the same.  17 Q. That's my question. Did you go  18 through, and did you measure all the filaments  19 in Mrs. Edwards' TVT-O mesh that you looked at?  20 A. No. Didn't answer any questions,  21 approximately I measured range.  22 Q. I guess what I'm getting at is when  23 you say you measured it, do you mean you  24 eyeballed it and measured it, or you measured it  25 with some type of tool?</p>	<p>1 your office?  2 A. Yes.  3 MR. SNELL: I think I asked, but just  4 note a request to produce.  5 BY MR. SNELL:  6 Q. Under Figure 1a you talk about "The  7 nerve branches enter between the mesh filaments  8 and grow into the spaces of mesh structure-nerve  9 ingrowth since the spaces were created by the  10 mesh placement during surgery."  11 Do you see that?  12 A. Yes.  13 Q. When you write "The spaces were  14 created by the mesh placement during surgery,"  15 do you understand that the space where the mesh  16 is placed is actually a space that's there  17 before the surgery?  18 A. No. There are no space before. There  19 is solid tissue, then there is an incision, and  20 then mesh is placed. Therefore that space,  21 newly created during the incision, is filled by  22 the mesh, and then tissue has to ingrow in that  23 space that's introduced by the mesh.  24 Q. Can you explain to me how it is --  25 strike that.</p>
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<p>1 A. Micrometer, tool, in the eyepiece. So  2 you use scale in the eyepiece, and then you use  3 magnification factor objective, and then you  4 measure.  5 Q. So Figure 1a, the microscope that you  6 looked at -- strike that.  7 The microscope you used to look at  8 Mrs. Edwards' specimens, what were the different  9 power options you had on that microscope?  10 A. One -- objectives, not --  11 Q. Objectives, yes.  12 A. Objective magnification factors --  13 magnifications were times 1, 2.5, 4, 10, 25, 40,  14 100.  15 Q. And can you estimate which one you  16 were using for Figure 1a?  17 A. Close to 10. Maybe 25. It all  18 depends on cropping factor, because if the  19 picture was large and I just cropped. Sometimes  20 you have to choose because not all objectives  21 are flat, sometimes it's darker corner, so it's  22 better to take a picture with lower  23 magnification and then crop it, and for some  24 magnification you go just to specific objective.  25 Q. But you have all these photographs at</p>	<p>1 Can you explain to me your  2 understanding of how a TVT-O mesh is put into  3 the body?  4 A. There is an incision, and then a  5 trocar is being pulled through the tissue.  6 Q. Where is the incision?  7 A. Incision is -- I think one is in skin,  8 and the one is in the vaginal wall.  9 Q. Is it a through-and-through incision  10 through the vaginal wall, or is it only partway  11 through?  12 A. The mucosa is incised through, so it's  13 not just epithelial, the mucosa transect.  14 Q. So the full thickness of the vaginal  15 wall is transacted during the TVT placement?  16 A. Not vaginal wall, mucosa.  17 Q. Does the mesh get placed -- so to your  18 understanding, if you think of the vagina, the  19 surgeon, to your understanding, does not dissect  20 all the way through the vaginal wall to put the  21 mesh up behind it and below the mid urethra, is  22 that your understanding?  23 A. It's placed somewhere in that space  24 between urethra and the mucosa. Again, there is  25 no hard anatomical structure to limit you either</p>

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<p>1 way. Mucosa is an anatomical structure you can</p> <p>2 see. Urethral wall anatomical structure you can</p> <p>3 see and feel when it's dissected.</p> <p>4 So when the mucosa is opened, what you</p> <p>5 see, you actually see parts of vaginal wall, how</p> <p>6 deep you are in the vaginal wall is</p> <p>7 questionable. What is part of vaginal wall.</p> <p>8 Mucosa itself, some mucosal tissue, smooth</p> <p>9 muscle, everything, all tissue up to the urethra</p> <p>10 is vaginal wall. So mesh is placed within parts</p> <p>11 of the vaginal wall.</p> <p>12 Q. To your understanding, mesh is placed</p> <p>13 within parts of the vaginal wall?</p> <p>14 A. Repeat it?</p> <p>15 Q. To your understanding, the TVT-O mesh</p> <p>16 is placed within parts of the vaginal wall?</p> <p>17 A. Yes.</p> <p>18 Q. Have you ever performed a TVT?</p> <p>19 A. No.</p> <p>20 Q. Even in a cadaver lab setting?</p> <p>21 A. No.</p> <p>22 Q. Have you ever performed any type of</p> <p>23 urinary incontinence surgery?</p> <p>24 A. No.</p> <p>25 MS. THOMPSON: Lunch is here.</p>	<p>1 AFTERNOON SESSION</p> <p>2 1:37 O'CLOCK P.M.</p> <p>3</p> <p>4 (Whereupon, Iakovlev Exhibit Number 5,</p> <p>5 Chain of custody regarding Mrs.</p> <p>6 Edwards' mesh specimen, was marked for</p> <p>7 identification.)</p> <p>8 BY MR. SNELL:</p> <p>9 Q. Doctor, I've handed you Exhibit</p> <p>10 Number 5, which is the chain of custody that we</p> <p>11 received regarding Mrs. Edwards' mesh specimen.</p> <p>12 A. Yes.</p> <p>13 Q. Do you recognize that document to</p> <p>14 indeed be the chain of custody for Mrs. Edwards'</p> <p>15 mesh specimen?</p> <p>16 A. It wasn't the chain of custody which I</p> <p>17 signed, because it's not signed by me. The one</p> <p>18 on Page 3, that's signed by me. And Page 4 is</p> <p>19 also signed by me.</p> <p>20 Q. So when did you get Mrs. Edwards' mesh</p> <p>21 specimen?</p> <p>22 A. June 3, 2013.</p> <p>23 Q. June 3rd, 2013?</p> <p>24 A. Yes.</p> <p>25 Q. And you're referencing the third page?</p>
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<p>1 MR. SNELL: I'm hungry. Are you</p> <p>2 hungry?</p> <p>3 THE WITNESS: Yes.</p> <p>4 MR. SNELL: Let's eat then.</p> <p>5 (Whereupon, a luncheon recess was</p> <p>6 taken at 1:01 p.m.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 A. Yes.</p> <p>2 Q. On the first page you see "P.</p> <p>3 Tomkins," and a date of August 24, 2012 for</p> <p>4 Mrs. Edwards three H&amp;E slides being released to</p> <p>5 the Mueller Law Firm?</p> <p>6 A. Yes.</p> <p>7 Q. Do you know what transpired between</p> <p>8 August 24th, 2012 and June 3rd, 2013 with regard</p> <p>9 to Mrs. Edwards' slides?</p> <p>10 A. I don't know. But if those are</p> <p>11 slides, I received specimen in formalin. Are</p> <p>12 they the same specimens?</p> <p>13 Q. Do you know?</p> <p>14 A. I don't know.</p> <p>15 Q. On the third page, you were pointing</p> <p>16 to where you signed for the materials. Item</p> <p>17 number two indicates three H&amp;E slides?</p> <p>18 A. Yes.</p> <p>19 Q. Does that correspond to the three H&amp;E</p> <p>20 slides that are referenced on Page 1?</p> <p>21 A. I don't know. I would have to look at</p> <p>22 the slide identifiers. Most likely they are,</p> <p>23 but I don't know for sure.</p> <p>24 Q. So on June 3rd, 2013, you received one</p> <p>25 jar containing surgical mesh material with</p>

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<p>1 attached soft tissue in formalin?</p> <p>2 A. Yes.</p> <p>3 Q. And you received three H&amp;E slides?</p> <p>4 A. Yes.</p> <p>5 Q. Did the material come directly to you,</p> <p>6 or to someone else in your lab?</p> <p>7 A. Came directly to me.</p> <p>8 Q. And how long had Mrs. Edwards' explant</p> <p>9 material been in formalin after her surgical</p> <p>10 explant?</p> <p>11 A. I can trace it back to see what was</p> <p>12 the time of excision. I mean there's a clinical</p> <p>13 record of excision. It was January, 2012. So a</p> <p>14 year and a half.</p> <p>15 Q. So Mrs. Edwards' mesh material sat in</p> <p>16 formalin for about a year and a half before you</p> <p>17 came in possession of it?</p> <p>18 A. Yes. Jar in formalin. The H&amp;E slides</p> <p>19 were generated earlier.</p> <p>20 Q. Do you know who generated those H&amp;E</p> <p>21 slides?</p> <p>22 A. I would have to see the slides, where</p> <p>23 they came from, because institutional identifier</p> <p>24 sometimes are on the slides.</p> <p>25 Q. When you received the mesh material</p>	<p>1 didn't weigh it, correct?</p> <p>2 A. No.</p> <p>3 Q. You mentioned you analyzed it for its</p> <p>4 stiffness?</p> <p>5 A. Yeah.</p> <p>6 Q. How did you analyze it for stiffness?</p> <p>7 A. Just by palpation.</p> <p>8 Q. By using your fingers?</p> <p>9 A. Yes.</p> <p>10 Q. You didn't use any type of tool to aid</p> <p>11 you in the stiffness testing?</p> <p>12 A. No. It's not routinely done. As we</p> <p>13 discussed, numerical parameters are weight,</p> <p>14 linear dimensions, and volume. That's recorded</p> <p>15 in pathology.</p> <p>16 Q. And then you said you sectioned the</p> <p>17 mesh?</p> <p>18 A. Yes.</p> <p>19 Q. Did you section it before it was</p> <p>20 ultimately put in formalin?</p> <p>21 A. No.</p> <p>22 Q. I'm sorry.</p> <p>23 Did your section the mesh before it</p> <p>24 was put in paraffin?</p> <p>25 A. Yes. I would have to see how it was</p>
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<p>1 from Mrs. Edwards in the jar in formalin,</p> <p>2 June 3rd, 2013, what did you do with that</p> <p>3 explant?</p> <p>4 A. Took it out, took a gross photograph,</p> <p>5 I think I did -- I think gross photographs of</p> <p>6 all specimens, and then measured it, and then</p> <p>7 examined it grossly for what it contains,</p> <p>8 stiffness, any other physical parameters, then</p> <p>9 sectioned it and put for processing.</p> <p>10 And we discussed the processing that</p> <p>11 was done by diagnostic laboratory, accredited</p> <p>12 diagnostic laboratory by using standard</p> <p>13 operating procedures.</p> <p>14 Q. When you say you sectioned the mesh --</p> <p>15 strike that.</p> <p>16 You took the mesh out of the formalin,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. And you took photographs of it?</p> <p>20 A. Gross photographs.</p> <p>21 Q. And then you measured it, correct?</p> <p>22 A. Yes.</p> <p>23 Q. How did you measure it?</p> <p>24 A. With a ruler.</p> <p>25 Q. As we discussed earlier, though, you</p>	<p>1 sectioned in the path report, pathology reports.</p> <p>2 When they do it, the record all these</p> <p>3 procedures.</p> <p>4 Q. Which pathology report are you</p> <p>5 referencing; yours?</p> <p>6 A. Mine.</p> <p>7 Q. Did you bring your pathology report</p> <p>8 here today?</p> <p>9 A. I thought it was provided to you.</p> <p>10 Q. I don't have a pathology report from</p> <p>11 you.</p> <p>12 A. I didn't bring it today.</p> <p>13 Q. Just so I understand, after you do</p> <p>14 your stiffness and physical analysis, what</p> <p>15 happens from that point until when you section</p> <p>16 it?</p> <p>17 A. Nothing. I take it out, palpate it,</p> <p>18 examine for whatever is inside, into the mesh,</p> <p>19 if there is any nodule, tumor, mass,</p> <p>20 hemorrhagic, describe the characteristics sort</p> <p>21 of. And then I decide what is the best way to</p> <p>22 section to examine for specific questions.</p> <p>23 So for mesh, my initial thoughts were</p> <p>24 imbedding it perpendicular on the edge might be</p> <p>25 the best way of doing it. Now I think flat</p>

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<p>1 gives you large area for its clinical features.  2 So it's a judgment call for pathologists.  3 And then the entire specimen is just  4 put in the cassette, or it's being sectioned and  5 then pieces are put in the cassette, and then  6 the cassette goes into the machine for  7 processing.  8 Q. How is the specimen processed?  9 A. Specimen processing is when specimen  10 is gradually dehydrated and then saturated by  11 softened blocks, or paraffin.  12 Q. Were you the one who does the gradual  13 dehydration of Mrs. Edwards' mesh?  14 A. No. It's done by a machine in the  15 lab. There is a processing machine.  16 Q. What machine is that?  17 A. You mean model?  18 Q. If you know.  19 A. I don't know. I mean it's a standard  20 machine. We have several machines.  21 Q. Do you know what the steps are in the  22 dehydration process that you subjected  23 Mrs. Edwards' explant to?  24 A. What usually is done -- not usually.  25 What is done by standard operating procedure, it</p>	<p>1 this same standard operating procedure to  2 gradually dehydrate the explant before putting  3 it into paraffin?  4 A. Yes. Not just explanted meshes. I  5 also did the same procedure for new mesh.  6 Q. Okay. Now, the alcohol solution is  7 ultimately increased up to 100 percent?  8 A. Yes.  9 Q. Okay. And during the dehydration  10 process, you testified that the alcohol is then  11 replaced by xylene?  12 A. Yes.  13 Q. What is xylene?  14 A. It's a solvent.  15 Q. I'm not a chemist, I'm sorry.  16 A. It's a solvent. I mean it's like any  17 solvent, chemical -- organic chemical solvent.  18 Q. Does the solvent dry out the tissue?  19 A. It's already dry. Dehydration. If  20 you mean drying as in dehydration, it's already  21 dehydrated. It is fluid, it's liquid, but it's  22 not water.  23 Q. What was the concentrations of the  24 xylene that were used in the process to prepare  25 Mrs. Edwards' mesh explant?</p>
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<p>1 goes through several solutions of formalin, so  2 first formalin circulates in the machine, then  3 this formalin is being replaced by solution of  4 an alcohol, gradually becomes 100 percent  5 alcohol. The alcohol is a soluble substance,  6 but is not exactly water. So at that stage the  7 specimen tissue becomes dehydrated, but still  8 immersed in fluid. And then alcohol is being  9 replaced by xylene again in several solutions,  10 because xylene is a solvent for paraffin. Then  11 when tissue is fully saturated by xylene,  12 paraffin can saturate it together with xylene.  13 And then the cassettes are being taken  14 out, and then tissue is put in the cassettes for  15 paraffin blocks. Not in the cassettes, in the  16 bowls, the paraffin blocks. It's a routine  17 protocol that's been in use for over 100 years.  18 Q. Do you have a written protocol for how  19 Mrs. Edwards' mesh was processed and dehydrated?  20 A. There is a standard operating  21 procedure. It was done by standard operating  22 procedure. Not just Mrs. Edwards specimen, any  23 specimen is processed by these procedures.  24 Q. All of the litigation transvaginal  25 mesh specimens that you analyzed went through</p>	<p>1 A. Xylene is a pure substance. It's not  2 dissolved in any other substance. It may have  3 traces of something, some other solvents, but...  4 Q. You said that the explant was  5 submitted to -- or strike that.  6 You said the explant was subjected to  7 several circulations of formalin?  8 A. Yes. Or solutions, or containers.  9 And the machine takes fluid from the container  10 and circulates within to wash all the specimens,  11 and then the fluid is being collected back, and  12 then the container is used to replace previous  13 solution and so forth. It cycles.  14 Q. How many cycles are involved with the  15 circulation of formalin?  16 A. I think at least three. It's standard  17 operating procedures.  18 Q. Do you know how long this at least  19 three cycles took for the circulation of the  20 formalin of Mrs. Edwards' explant?  21 A. This process can be interrupted. It  22 can be anywhere from 72 hours to two hours. If  23 the specimens are loaded Friday, they remain in  24 formalin up until evening/afternoon of Sunday,  25 and then the cycles starts in.</p>

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<p>1 Q. The exposure to the alcohol -- strike</p> <p>2 that.</p> <p>3 The explant is exposed to different</p> <p>4 concentrations of alcohol as you testified to,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Are those done in different cycles as</p> <p>8 well?</p> <p>9 A. The alcohol steps follow formalin, so</p> <p>10 there are several solutions. First it will be</p> <p>11 lower concentration of alcohol, I think</p> <p>12 75 percent, then next solution becomes 85 or 80,</p> <p>13 and then 90, 95, and then 100 percent. So it's</p> <p>14 increasing concentration. I don't remember</p> <p>15 exactly how many, but it will be increasing</p> <p>16 concentration up to 100 percent pure alcohol.</p> <p>17 Q. Do you know for how long the -- strike</p> <p>18 that.</p> <p>19 Do you know for how long Mrs. Edwards'</p> <p>20 mesh explant was exposed to the different</p> <p>21 alcohol concentrations?</p> <p>22 A. No. I would have to check with the</p> <p>23 procedures.</p> <p>24 Q. And then the alcohol was replaced by</p> <p>25 xylene, which is a solvent, as you testified to,</p>	<p>1 replaced by xylene, there is traces of alcohol,</p> <p>2 so then alcohol is being washed by several</p> <p>3 cycles of xylene. So one fluid -- one container</p> <p>4 is used with xylene, but once it goes through</p> <p>5 specimens, it absorbs some alcohol and then</p> <p>6 there's a mixture, a little bit of alcohol, more</p> <p>7 xylene. So then all is drained, and then the</p> <p>8 whole machine is filled with xylene again, so</p> <p>9 there is much less traces of alcohol and there</p> <p>10 are more xylene. And then this is drained</p> <p>11 again, and then a new solution is used. So that</p> <p>12 last step, usually third step is practically all</p> <p>13 just xylene without traces of alcohol.</p> <p>14 Q. So the xylene helps remove the</p> <p>15 alcohol?</p> <p>16 A. Yes. It removes alcohol.</p> <p>17 Q. Okay.</p> <p>18 A. Replaces it.</p> <p>19 Q. And as the cassette, Mrs. Edwards'</p> <p>20 cassette tissue specimen is exposed to more and</p> <p>21 more xylene, the alcohol goes away, and at the</p> <p>22 end you're left with pretty much pure xylene?</p> <p>23 A. Yes.</p> <p>24 Q. Is a single machine used for this</p> <p>25 process we've described of going through the</p>
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<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And how is the mesh explant exposed to</p> <p>4 xylene?</p> <p>5 A. The same way. I mean contained within</p> <p>6 cassettes, and fluid circulates through baskets</p> <p>7 filled with these cassettes from different</p> <p>8 specimens. The machine is loaded by anywhere</p> <p>9 between 20 to 100 of cassettes from different</p> <p>10 patients, and everything is being processed in</p> <p>11 the same time.</p> <p>12 Q. And how long was Mrs. Edwards' explant</p> <p>13 exposed to the xylene?</p> <p>14 A. I would have to check for standard</p> <p>15 procedures. It's a standard procedure. There</p> <p>16 was nothing modified for Ms. Edwards.</p> <p>17 Q. Do you have an understanding about</p> <p>18 whether it was for minutes, hours, days?</p> <p>19 A. Hours. More hours than days or</p> <p>20 minutes.</p> <p>21 Q. And the xylene is a pure substance, so</p> <p>22 Mrs. Edwards' explant wasn't submitted to</p> <p>23 different solutions of xylene, it was just</p> <p>24 submitted to different cycles of xylene?</p> <p>25 A. See, when the alcohol is being</p>	<p>1 circulation of the formalin to alcohol</p> <p>2 solutions, the xylene exposure, for</p> <p>3 Mrs. Edwards' mesh?</p> <p>4 A. It's all done in one machine. I mean</p> <p>5 the cycle is all done in one machine.</p> <p>6 Q. And that's a machine inside your lab?</p> <p>7 A. Yes.</p> <p>8 Q. Are there certain temperature controls</p> <p>9 within that machine during this process we've</p> <p>10 been discussing for Mrs. Edwards' mesh?</p> <p>11 A. Yes, it's strictly controlled.</p> <p>12 Q. Do you know what the temperature</p> <p>13 control is?</p> <p>14 A. For different stages it's different,</p> <p>15 and you would have to go through the procedure.</p> <p>16 It's programmed into the machine.</p> <p>17 Q. It would be laid out in the standard</p> <p>18 operating protocol you described?</p> <p>19 A. Yes. Or a manual for the machine.</p> <p>20 And I believe it would be the same anywhere in</p> <p>21 the diagnostic labs.</p> <p>22 Q. I believe you testified then the</p> <p>23 explant is exposed to paraffin?</p> <p>24 A. Yes.</p> <p>25 Q. Is xylene still on the explant when</p>

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<p>1 it's exposed to paraffin?</p> <p>2 A. There might be some traces, because</p> <p>3 xylene is a solvent for paraffin, so xylene can</p> <p>4 dissolve paraffin. When it's fully saturated</p> <p>5 with xylene, then you can saturate it with</p> <p>6 paraffin, because paraffin is being dissolved by</p> <p>7 xylene. So you replace it with paraffin.</p> <p>8 Q. Was Mrs. Edwards' explant fully</p> <p>9 saturated with xylene at the end of the xylene</p> <p>10 cycles?</p> <p>11 A. Yes.</p> <p>12 Q. What was the temperature of the</p> <p>13 paraffin that was put onto Mrs. Edwards' mesh</p> <p>14 explant?</p> <p>15 A. It goes up to melting point of</p> <p>16 paraffin. I think it might be up to 90 degrees</p> <p>17 centigrade.</p> <p>18 Q. So the paraffin that was put onto</p> <p>19 Mrs. Edwards' mesh was at a temperature of up to</p> <p>20 90 degrees centigrade?</p> <p>21 A. Yes.</p> <p>22 Q. And --</p> <p>23 A. Depends on the paraffin. Some</p> <p>24 paraffins need lower melting temperature, they</p> <p>25 are have mixed, pre-mixed, so it's a little</p>	<p>1 Q. And that exposure to the cooling can</p> <p>2 differ, depending upon the level at which it's</p> <p>3 in this machine?</p> <p>4 A. No. The time when the technologist --</p> <p>5 just because they are sitting in paraffin when</p> <p>6 the technologist is working. So that period is</p> <p>7 variable for cassettes.</p> <p>8 Q. What is the makeup of the paraffin</p> <p>9 that you use for Mrs. Edwards' mesh?</p> <p>10 A. I don't know exact concentration,</p> <p>11 proportions of paraffins, because some paraffins</p> <p>12 have slightly different physical</p> <p>13 characteristics. It's somewhere in the</p> <p>14 operating procedures. It's a diagnostic grade</p> <p>15 of paraffin.</p> <p>16 Q. Okay. Do you know where your hospital</p> <p>17 would have gotten the paraffin from that was</p> <p>18 used in Mrs. Edwards' explanted mesh?</p> <p>19 A. I can check with the record. I mean</p> <p>20 every time they buy they have record.</p> <p>21 Q. Would it show the one that</p> <p>22 Mrs. Edwards was exposed to?</p> <p>23 A. We can see what was -- and where it</p> <p>24 was bought at that time, if there is a record.</p> <p>25 I mean there should be a record.</p>
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<p>1 different, it's a little different. But roughly</p> <p>2 90 degrees, around that.</p> <p>3 Q. And how long does the explant stay in</p> <p>4 the paraffin until -- strike that.</p> <p>5 The melted paraffin ultimately sets</p> <p>6 into a block, correct?</p> <p>7 A. Yes.</p> <p>8 Q. How long does it take for</p> <p>9 Mrs. Edwards' explant to go from being exposed</p> <p>10 to the hot, melted paraffin to a block?</p> <p>11 A. I don't know. Sometimes it's</p> <p>12 variable, so I would have to check with</p> <p>13 procedures. It's not that long. Minutes, I</p> <p>14 would say. But again, I would have to check</p> <p>15 with standard operating procedures.</p> <p>16 Mostly depends how they imbed them,</p> <p>17 because they are sitting in this liquified</p> <p>18 paraffin, and technology is imbedded. So if</p> <p>19 it's the first cassette, it will take many</p> <p>20 minutes. But if it's a cassette on bottom, it</p> <p>21 may take more than an hour.</p> <p>22 Q. Are they submitted -- strike that.</p> <p>23 Are the cassettes exposed to some type</p> <p>24 of cooling mechanism to set the paraffin?</p> <p>25 A. Yes.</p>	<p>1 Q. The testing that you did for</p> <p>2 degradation of Mrs. Edwards' mesh, was that done</p> <p>3 after the mesh was put in paraffin?</p> <p>4 A. Testing of degradation wasn't just</p> <p>5 done on Ms. Edwards', because testing of</p> <p>6 degradation and the process with controls</p> <p>7 analysis comparison with -- of different</p> <p>8 specimens. So the specimens which are analyzed</p> <p>9 by microscope, they are all going through the</p> <p>10 same processing steps as we discussed. So</p> <p>11 Ms. Edwards' specimen went through all these</p> <p>12 steps, as well as other specimens, as well as</p> <p>13 controls of new mesh.</p> <p>14 Q. Let's focus on Mrs. Edwards</p> <p>15 specifically, though.</p> <p>16 The degradation analysis you did</p> <p>17 regarding Mrs. Edwards' mesh was an analysis</p> <p>18 done with microscope, correct?</p> <p>19 A. I detected. It wasn't analysis.</p> <p>20 Analysis of degradation process was not done on</p> <p>21 one patient. So to make conclusion of the</p> <p>22 degradation it needed examination of several</p> <p>23 specimens looking for specific features, and</p> <p>24 compare this with control samples, which are --</p> <p>25 which were new meshes subjected to the same</p>

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<p>1 formalin fixation and processing steps.</p> <p>2 Q. You said you didn't do degradation</p> <p>3 testing, you did --</p> <p>4 A. Detection.</p> <p>5 Q. -- detection.</p> <p>6 Okay. So the degradation detection</p> <p>7 you did specific to Mrs. Edwards' mesh was done</p> <p>8 when you looked through the microscope at her</p> <p>9 specimens?</p> <p>10 A. Yes.</p> <p>11 Q. And that detection, looking through</p> <p>12 the microscope, was done obviously after the</p> <p>13 specimen had been first exposed to formalin and</p> <p>14 then put in paraffin, in the paraffin set,</p> <p>15 correct?</p> <p>16 A. Yes. But the way you presenting it is</p> <p>17 misrepresenting the analysis. Because if they</p> <p>18 go to analysis of degradation, you cannot base</p> <p>19 it on one patient. Once you do analysis, you</p> <p>20 identify features which are reflecting</p> <p>21 degradation, then you can detect it in other</p> <p>22 specimens. That's what was done for</p> <p>23 Ms. Edwards. Once I performed analysis of</p> <p>24 degradation process, then I could detect it in</p> <p>25 Ms. Edwards.</p>	<p>1 A. No.</p> <p>2 Q. -- about the processing?</p> <p>3 A. No.</p> <p>4 Q. Did you imbed the entire specimens</p> <p>5 received on Mrs. Edwards into the paraffin?</p> <p>6 A. I think so. I would need to go and</p> <p>7 check. Sometimes I preserve, and then most of</p> <p>8 the samples for this litigation were divided in</p> <p>9 half once we had protocol that samples need to</p> <p>10 be divided in half, and one half need to be</p> <p>11 preserved. So I would need to check if for</p> <p>12 Ms. Edwards we already had that protocol, or we</p> <p>13 didn't have that protocol.</p> <p>14 Q. Is this a written protocol, it sounds</p> <p>15 like, you had?</p> <p>16 A. It was -- well, it was written for at</p> <p>17 least one trial, for one litigation.</p> <p>18 Q. You don't happen to have a copy of</p> <p>19 that protocol here today?</p> <p>20 A. It was for different litigation.</p> <p>21 MR. SNELL: I note request to produce.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. For the different solvents/chemicals</p> <p>24 that Mrs. Edwards' mesh was exposed to, did you</p> <p>25 consult with anybody else about what particular</p>
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<p>1 Q. You described the way in which</p> <p>2 Mrs. Edwards' mesh was processed from the time</p> <p>3 you got it until the time it was put into the</p> <p>4 paraffin blocks and set. Did you consult with</p> <p>5 anyone about that process and how it should take</p> <p>6 place?</p> <p>7 A. This is standard process of</p> <p>8 microscopic examination.</p> <p>9 Q. So the answer is no, you didn't</p> <p>10 consult with anyone, correct?</p> <p>11 A. No.</p> <p>12 Q. Did you consult with any polymer</p> <p>13 chemist?</p> <p>14 A. No.</p> <p>15 Q. Did you consult with any material</p> <p>16 scientist?</p> <p>17 A. No.</p> <p>18 Q. Did you talk with any of the other</p> <p>19 Plaintiffs' experts?</p> <p>20 A. Regarding process?</p> <p>21 Q. Yes.</p> <p>22 A. This is the only process which enables</p> <p>23 you to see things under microscope.</p> <p>24 Q. So the answer is you didn't talk to</p> <p>25 any of the Plaintiffs' experts, correct --</p>	<p>1 chemicals and concentrations should be used</p> <p>2 during that process?</p> <p>3 A. No. It's standard process, so I used</p> <p>4 standard process. The most important question</p> <p>5 is if controls were exposed to the same steps,</p> <p>6 which they were.</p> <p>7 Q. For Mrs. Edwards' mesh, why didn't you</p> <p>8 leave half of it in formalin for us to look at?</p> <p>9 A. Because we didn't have that product.</p> <p>10 I was not told that specimens for litigation</p> <p>11 process may need another half for Defendants'</p> <p>12 experts. Once the protocol was formally set,</p> <p>13 then I was processing all specimens in the same</p> <p>14 fashion. And later specimens, they were all</p> <p>15 divided.</p> <p>16 Q. When did you process Mrs. Edwards'</p> <p>17 specimens?</p> <p>18 A. In June, 2013.</p> <p>19 Q. For the paraffin blocks that you made</p> <p>20 for Mrs. Edwards' specimens, did you cut through</p> <p>21 all of the blocks when you did your analyses?</p> <p>22 A. No, the blocks were not exhausted,</p> <p>23 there's still tissue, must be still tissue in</p> <p>24 the blocks.</p> <p>25 Q. Did you take samples from each of the</p>

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<p>1 blocks?</p> <p>2 A. If block is produced there is a slide,</p> <p>3 so each block is being sectioned. I had slides</p> <p>4 for each block. It could have been only one</p> <p>5 block or it could have been more than one, but</p> <p>6 if there's a block there's a slide.</p> <p>7 (Whereupon, Iakovlev Exhibit Number 6,</p> <p>8 Slide of paraffin blocks from Mrs.</p> <p>9 Edwards' explant, was marked for</p> <p>10 identification.)</p> <p>11 BY MR. SNELL:</p> <p>12 Q. Handing you Exhibit Number 6</p> <p>13 (handing).</p> <p>14 A. Yes.</p> <p>15 Q. Do you recognize these to be the</p> <p>16 paraffin blocks from Mrs. Edwards' explant that</p> <p>17 you prepared?</p> <p>18 A. There is no identifier. I can see</p> <p>19 it's Ethicon mesh because it's blue.</p> <p>20 (Whereupon, Iakovlev Exhibit Number 7,</p> <p>21 Slides of paraffin block of Ms.</p> <p>22 Edwards' explant, was marked for</p> <p>23 identification.)</p> <p>24 A. There are two blocks. If they're the</p> <p>25 same.</p>	<p>1 which mirrors the tissue appearance in the</p> <p>2 block?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Turn to the second page.</p> <p>5 Similar to the first page; do you recognize this</p> <p>6 to be another block?</p> <p>7 A. Yes.</p> <p>8 Q. With a slide that has tissue which</p> <p>9 mirrors the shape of the block?</p> <p>10 A. Yes.</p> <p>11 Q. And although the label is cut off</p> <p>12 above, does that also appear to be a</p> <p>13 St. Michael's slide, have the same lot number,</p> <p>14 40193?</p> <p>15 A. Looks like it, yes.</p> <p>16 Q. So having seen Exhibit 7, you made two</p> <p>17 blocks of paraffin tissue with Mrs. Edwards'</p> <p>18 explant in it?</p> <p>19 A. By this exhibit, it looks like that,</p> <p>20 yes. But I would have to check with my</p> <p>21 pathology report. It's most likely only two</p> <p>22 blocks.</p> <p>23 Q. Go back to the chain of custody</p> <p>24 exhibit, the very last page.</p> <p>25 A. Emory Med Labs material, and the next</p>
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<p>1 BY MR. SNELL:</p> <p>2 Q. Take a look at Exhibit Number 7.</p> <p>3 A. That's a slide, but the block is</p> <p>4 not -- I mean the outlines of the tissue are the</p> <p>5 same, so I assume that this is, yes.</p> <p>6 Q. So Exhibit Number 7 has the blocks on</p> <p>7 the front page to the left, and then a slide to</p> <p>8 the right of that, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And you see it says "Edwards, Tonya"</p> <p>11 up above, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Where was this slide made?</p> <p>14 A. That's St. Michael's Hospital label.</p> <p>15 Q. Your hospital?</p> <p>16 A. Yes.</p> <p>17 Q. A slide you made?</p> <p>18 A. My lab made.</p> <p>19 Q. What's the blue line?</p> <p>20 A. Control. Immunohistochemical control.</p> <p>21 Q. So you made the blue line there?</p> <p>22 A. No. The technologist.</p> <p>23 Q. So the specimen above is the control?</p> <p>24 A. Yes.</p> <p>25 Q. Below is the specimen from the block</p>	<p>1 line is St. Michael's Hospital, 1a and -- yes,</p> <p>2 they were only two blocks.</p> <p>3 Q. Okay. So for Mrs. Edwards' mesh</p> <p>4 specimen, you processed -- you ended up</p> <p>5 processing it into two paraffin blocks labeled</p> <p>6 1a and 1b?</p> <p>7 A. Yes. That's correct.</p> <p>8 Q. And you took sections from both blocks</p> <p>9 1a and 1b of Mrs. Edwards' mesh explant,</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And if you look at Exhibit Number 6</p> <p>13 and 7 --</p> <p>14 A. Yes.</p> <p>15 Q. -- does it appear that you</p> <p>16 sectioned -- strike that.</p> <p>17 Looking at Exhibit 6 and 7, does it</p> <p>18 appear that you set the mesh specimen</p> <p>19 perpendicular in the formalin?</p> <p>20 A. It's on edge, or most of the specimen</p> <p>21 is on edge. I mean it's hard to define where</p> <p>22 edge is of a round structure.</p> <p>23 Q. Mrs. Edwards' mesh explant that you</p> <p>24 received, did it have protein on it?</p> <p>25 A. Human tissue is mostly protein.</p>

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<p>1 Q. So Mrs. Edwards' mesh explant had</p> <p>2 obviously human tissue on it, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And this human tissue contains</p> <p>5 protein, correct?</p> <p>6 A. Yes.</p> <p>7 Q. It was exposed to the formalin with</p> <p>8 the tissue on it, correct?</p> <p>9 A. "It" meaning mesh, yes.</p> <p>10 Q. The explant, yes.</p> <p>11 A. Yes.</p> <p>12 Q. Is formaldehyde a substance which</p> <p>13 naturally occurs in the body?</p> <p>14 A. Maybe in very small amounts.</p> <p>15 Q. Which --</p> <p>16 A. Very small amounts.</p> <p>17 Q. Which organ would produce formaldehyde</p> <p>18 in the human body?</p> <p>19 A. Might be -- I would have to check, but</p> <p>20 it might be a product of when the liver is</p> <p>21 metabolizing some substances and toxins. But if</p> <p>22 it is, it will be very small amount. I know the</p> <p>23 body's producing some aldehydes. If any of</p> <p>24 those aldehydes are containing the same tail as</p> <p>25 formaldehyde, I don't know for sure. But human</p>	<p>1 or any tools to manipulate the mesh during the</p> <p>2 processing steps?</p> <p>3 A. During imbedding it's usually handled</p> <p>4 by forceps. I -- depending on -- sometimes I</p> <p>5 just section it and handle it with my fingers.</p> <p>6 Depends.</p> <p>7 Q. Would you wear gloves?</p> <p>8 A. Yes, always. New, new gloves out of</p> <p>9 the package.</p> <p>10 Q. Do proteins have oxygen in them?</p> <p>11 A. Yes. I mean there is oxygen.</p> <p>12 You mean oxygen as oxygen gas, or</p> <p>13 oxygen as oxygen atoms.</p> <p>14 Q. Oxygen atoms, correct.</p> <p>15 A. Yes.</p> <p>16 Q. For Mrs. Edwards' explant, you didn't</p> <p>17 do any energy dispersion spectrometry testing?</p> <p>18 A. That's outside of my field.</p> <p>19 Q. You did not do any scanning electron</p> <p>20 microscopy in Mrs. Edwards' case, correct?</p> <p>21 A. No. I did not do scanning electron</p> <p>22 microscopy.</p> <p>23 Q. The electron microscopy that you did</p> <p>24 look at -- strike that.</p> <p>25 The electron microscopy that you did</p>
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<p>1 body can produce aldehydes. Actually that's</p> <p>2 what people experience during hangover, because</p> <p>3 alcohol is being converted to aldehydes.</p> <p>4 Q. Water was removed from Mrs. Edwards'</p> <p>5 specimens during this processing?</p> <p>6 A. Yes.</p> <p>7 Q. How much water?</p> <p>8 A. All of it, or most of it.</p> <p>9 Q. Is it collected and weighed during the</p> <p>10 processes that you had employed?</p> <p>11 A. Water?</p> <p>12 Q. Yes.</p> <p>13 A. No.</p> <p>14 Q. The water weight.</p> <p>15 A. No.</p> <p>16 Q. Is water known as a universal solvent?</p> <p>17 A. Yes. It's a substance which dissolve</p> <p>18 most -- the most of the chemicals. I mean no</p> <p>19 other solvent can dissolve as many chemicals</p> <p>20 within.</p> <p>21 Q. Do you know if water is a known</p> <p>22 plasticizer, or is that an area outside of your</p> <p>23 field?</p> <p>24 A. It's an area outside of my field.</p> <p>25 Q. Okay. Did you use tweezers or forceps</p>	<p>1 do for Mrs. Edwards' explant was done after her</p> <p>2 samples had been dried out and set in paraffin,</p> <p>3 correct?</p> <p>4 A. I don't think I've done electron</p> <p>5 microscopy for Ms. Edwards.</p> <p>6 Q. Okay.</p> <p>7 A. I've done it on other Ethicon</p> <p>8 explants.</p> <p>9 Q. So you have not done any type of</p> <p>10 electron microscopy on Mrs. Edwards' explant?</p> <p>11 A. No.</p> <p>12 Q. You know that when formaldehyde bonds</p> <p>13 with protein polymers a new polymer is formed?</p> <p>14 A. Please repeat the question?</p> <p>15 Q. Sure.</p> <p>16 Do you know that when formaldehyde</p> <p>17 bonds with protein polymers a new polymer is</p> <p>18 formed?</p> <p>19 A. Protein polymer; I'm not sure what you</p> <p>20 mean.</p> <p>21 Q. Okay. Is that a field outside of your</p> <p>22 expertise?</p> <p>23 A. I'm not sure if such thing exists, a</p> <p>24 protein polymer. Maybe since any sort of</p> <p>25 setting, if you accept -- polymer is something</p>

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<p>1 with relatively homogeneous simple molecule</p> <p>2 which is being linked into continuous chains.</p> <p>3 Proteins are completely different structures.</p> <p>4 So I don't think this is a correct term.</p> <p>5 Q. When a chemical like formaldehyde --</p> <p>6 is it your field of expertise where you know</p> <p>7 whether when formaldehyde is exposed to</p> <p>8 proteins, whether they can bond?</p> <p>9 A. That's the role of formalin.</p> <p>10 Formaldehyde crosslinks proteins.</p> <p>11 Q. Okay.</p> <p>12 A. Protein becomes sort of tied up in</p> <p>13 specific sites.</p> <p>14 Q. The chemicals we talked about in the</p> <p>15 processing of Mrs. Edwards' specimen, the</p> <p>16 paraffin -- strike that.</p> <p>17 The chemicals and solutions we</p> <p>18 discussed which Mrs. Edwards' mesh specimen were</p> <p>19 subjected to, including the circulating</p> <p>20 formalin, the alcohol, the xylene, and the</p> <p>21 paraffin, is that the total of chemicals and</p> <p>22 solutions that her mesh was submitted to?</p> <p>23 A. Then there's staining, so there's</p> <p>24 chemicals during staining.</p> <p>25 Q. Before we get to staining, were there</p>	<p>1 Q. That's not something you consider</p> <p>2 yourself an expert on?</p> <p>3 A. No.</p> <p>4 Q. Have you ever -- just so I'm clear,</p> <p>5 you've never prepared a mesh for chemical</p> <p>6 processing and testing?</p> <p>7 A. For those specific tests, no. I</p> <p>8 prepared one sample, as we discussed earlier, as</p> <p>9 a part of XPS analysis. I prepared the sample</p> <p>10 for XPS analysis.</p> <p>11 Q. XPS?</p> <p>12 A. XPS.</p> <p>13 Q. What is that?</p> <p>14 A. That's a spectroanalysis of x-ray, I</p> <p>15 think, radiation, or based on x-ray principles.</p> <p>16 Q. How was it that you came to prepare</p> <p>17 that sample?</p> <p>18 A. I happened to receive the sample,</p> <p>19 which was in dry jar and devoid of tissue and</p> <p>20 not exposed to formalin, the jar wasn't labeled</p> <p>21 as formalin, so it was a good opportunity to</p> <p>22 test it. No formalin exposure, clean filaments</p> <p>23 without tissue.</p> <p>24 Q. That's not something you did for TVT-O</p> <p>25 mesh?</p>
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<p>1 any others?</p> <p>2 A. That's it. That's it.</p> <p>3 Q. Okay. Have you ever been involved in</p> <p>4 doing any chemical analyses of meshes?</p> <p>5 A. Well, we have to define what is</p> <p>6 chemical analysis. When I stain it, is it</p> <p>7 chemical analysis, and look at it under a</p> <p>8 microscope?</p> <p>9 Q. No.</p> <p>10 A. You mean specific like XPS analysis?</p> <p>11 No.</p> <p>12 Q. Have you ever done FTIR testing on</p> <p>13 meshes?</p> <p>14 A. No.</p> <p>15 Q. Is that something you were ever</p> <p>16 trained on?</p> <p>17 A. No.</p> <p>18 Q. Okay. You understand that there are</p> <p>19 chemical tests that experts in other disciplines</p> <p>20 use to analyze chemicals like FTIR testing?</p> <p>21 A. Yes, I heard -- I saw some</p> <p>22 publications that were done and can be used.</p> <p>23 Q. But that's not something that you</p> <p>24 regularly do in your course of work?</p> <p>25 A. No.</p>	<p>1 A. It was not TVT-O mesh.</p> <p>2 Q. What type of mesh was that?</p> <p>3 A. It was a sling of other manufacturer,</p> <p>4 but I don't remember which manufacturer.</p> <p>5 Q. Did it have tissue on it?</p> <p>6 A. Partially yes, partially no. The end</p> <p>7 filaments were clean.</p> <p>8 Q. Did you consult any literature or text</p> <p>9 when you did the preparation of that sling</p> <p>10 sample?</p> <p>11 A. No. The preparation was pretty</p> <p>12 simple, cut off the ends and separate them in</p> <p>13 two groups, scratch the surface on one group,</p> <p>14 and leave the other group not altered.</p> <p>15 Q. Let's go back to Page 18 in your</p> <p>16 report. I'm sorry, go back even further.</p> <p>17 A. Yes.</p> <p>18 Q. So we were looking at Figure 1a,</p> <p>19 "Nerve Ingrowth."</p> <p>20 A. Which page?</p> <p>21 Q. Page 12.</p> <p>22 A. Page 12.</p> <p>23 Q. So if we're looking at Page 12, you</p> <p>24 see there are two holes where the mesh pores</p> <p>25 were?</p>

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<p>1 A. There are five holes.</p> <p>2 Q. I'm talking about --</p> <p>3 A. "Hole" as hole left by the mesh</p> <p>4 filaments in the tissue, or hole between mesh</p> <p>5 filaments?</p> <p>6 Q. I'm talking about -- first to orient</p> <p>7 ourself, let's back up and see if we can reach</p> <p>8 an agreement.</p> <p>9 Tissue is cut with a microtome,</p> <p>10 right --</p> <p>11 A. Yes.</p> <p>12 Q. -- four or seven microns thick usually</p> <p>13 when you're looking at doing this type of</p> <p>14 microscopic analysis, right?</p> <p>15 A. Yes.</p> <p>16 Q. In your lab you cut it about 4</p> <p>17 microns, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And what happens is when you cut</p> <p>20 through the tissue, the mesh will actually fall</p> <p>21 out sometimes?</p> <p>22 A. Cross-sections of the filaments fall</p> <p>23 out, yes.</p> <p>24 Q. Sometimes there can be some filament</p> <p>25 left in that hole?</p>	<p>1 the tissue. I don't know if there is no</p> <p>2 filaments left in there. How do you know?</p> <p>3 Q. Well, it's your report, so you tell</p> <p>4 me.</p> <p>5 Are there filaments left in there?</p> <p>6 A. Because some of them are transparent</p> <p>7 so you cannot see, you have to polarize just to</p> <p>8 see if polypropylene is still there. Most of</p> <p>9 them fall out.</p> <p>10 Q. Do you know if polypropylene is still</p> <p>11 there for Figure 1a?</p> <p>12 A. I would have to go back to the slide,</p> <p>13 put it on the stage, use polarizer, and see if</p> <p>14 it's there. Without polarizer it's very</p> <p>15 difficult, unless it's blue. If it's blue, then</p> <p>16 you can see the color. But Ethicon meshes are</p> <p>17 done by two filaments, one blue, one clear, so</p> <p>18 clear ones wouldn't be visible.</p> <p>19 Q. Now, those two filaments of mesh, what</p> <p>20 is that in-between them?</p> <p>21 A. In-between them?</p> <p>22 Q. Yes.</p> <p>23 A. They're almost touching.</p> <p>24 Q. Right. But they're not quite</p> <p>25 touching, correct?</p>
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<p>1 A. Yes.</p> <p>2 Q. But sometimes, many times it falls</p> <p>3 out, correct?</p> <p>4 A. Yes.</p> <p>5 Q. All right. So just to orient</p> <p>6 ourselves, we're looking at the two holes that</p> <p>7 are almost stacked vertically in the middle of</p> <p>8 the page.</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Those are two different mesh</p> <p>11 fibers that were present?</p> <p>12 A. Let's call them filaments.</p> <p>13 Q. Okay. We'll use whatever word you're</p> <p>14 comfortable with.</p> <p>15 A. Because they are called monofilament</p> <p>16 meshes, so I think filament is more appropriate.</p> <p>17 Q. So the polypropylene TVT-O meshes is a</p> <p>18 monofilament mesh?</p> <p>19 A. Yes.</p> <p>20 Q. Now, these two filaments that we're</p> <p>21 looking at which appear to be close together and</p> <p>22 oriented vertically in Figure 1a, those were</p> <p>23 parts where the TVT-O mesh were before</p> <p>24 sectioning, correct?</p> <p>25 A. Yes. I mean these are holes left in</p>	<p>1 A. No.</p> <p>2 Q. What is that in-between them?</p> <p>3 A. I would have to go high power and look</p> <p>4 in the microscope. There can be inflammatory</p> <p>5 cell, a little bit of collagen, some in specific</p> <p>6 fluids, serum. It depends. I mean I would have</p> <p>7 to investigate, have a look, maybe stain.</p> <p>8 Q. There's tissue in-between those two</p> <p>9 filaments, correct?</p> <p>10 A. Tissue components, yes.</p> <p>11 Q. And what's that distance between those</p> <p>12 two filaments?</p> <p>13 A. I would have to measure it. It looks</p> <p>14 like there's at least one inflammatory cell, and</p> <p>15 a little bit more of that, so my guess would be</p> <p>16 at least 20 microns.</p> <p>17 Q. So your best estimate, using cells as</p> <p>18 a scale --</p> <p>19 A. Yes.</p> <p>20 Q. -- the distance between those two mesh</p> <p>21 filaments is 20, 30 microns?</p> <p>22 A. Yes. At that level of sectioning,</p> <p>23 specifically happened about approximately 20</p> <p>24 microns.</p> <p>25 Q. And there are elements of tissue in</p>

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<p>1 that 20, 30-micron space?</p> <p>2 A. Maybe less, because sometimes it's</p> <p>3 getting jammed and so forth.</p> <p>4 Q. Okay. There's areas -- there's</p> <p>5 elements of tissue in that 20 to 30-micron</p> <p>6 space?</p> <p>7 A. Yes.</p> <p>8 Q. If you look at the left side picture,</p> <p>9 now I'm going to -- I want you to orient to this</p> <p>10 filament which is the top one that we were</p> <p>11 looking at --</p> <p>12 A. Yes.</p> <p>13 Q. -- here. The space next to it -- if I</p> <p>14 had your photos it would be easier. What I've</p> <p>15 drawn here, what is in this space which is to</p> <p>16 the right of the middle pore?</p> <p>17 A. So it's kind of clear?</p> <p>18 Q. Yes.</p> <p>19 A. It's hard to say. I would have to go</p> <p>20 back to the slide. It could be just a collagen,</p> <p>21 a singular collagen. Because collagen doesn't</p> <p>22 stain well with hematoxylin counterstain,</p> <p>23 immunostain, so anything clear on this image</p> <p>24 with this sort of quality of printing is either</p> <p>25 collagen or just empty space.</p>	<p>1 Q. What are those?</p> <p>2 A. Those are called twigs, nerve twigs.</p> <p>3 It's very, very small branches of nerves getting</p> <p>4 into practically one nerve fiber.</p> <p>5 Q. There are nerves that naturally occur</p> <p>6 in the vaginal tissue, correct?</p> <p>7 A. Yes. I mean all tissue has nerves.</p> <p>8 Q. To the left of the mesh filament which</p> <p>9 is in the bottom right corner --</p> <p>10 A. Yes.</p> <p>11 Q. -- you see there are clear areas,</p> <p>12 areas of white?</p> <p>13 A. Yes.</p> <p>14 Q. What is that? Are those spaces in</p> <p>15 connective tissue?</p> <p>16 A. Yes. This is just a separation during</p> <p>17 the processing. I would have to look in the</p> <p>18 microscope. But sometimes tissue gets little</p> <p>19 bit of retraction space when it's being</p> <p>20 processed, it retracts, so there's artificial</p> <p>21 empty space.</p> <p>22 Q. Is that what pathologists talk about</p> <p>23 when they reference artifacts from the</p> <p>24 processing?</p> <p>25 A. Yes. Retraction, tissue retraction is</p>
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<p>1 Q. Okay. Look at Figure 1b. Can you</p> <p>2 tell me; what's the magnification?</p> <p>3 A. This was probably done at 40. At</p> <p>4 least 25 objective. Probably 25.</p> <p>5 Q. If we're looking at the left slide,</p> <p>6 these brown --</p> <p>7 A. It's a nerve branch.</p> <p>8 Q. It's your opinion those are nerve</p> <p>9 branches?</p> <p>10 A. Yes.</p> <p>11 Q. Directly below them, do you see there</p> <p>12 are two shapes that have distinct morphologic</p> <p>13 appearances?</p> <p>14 A. Brown?</p> <p>15 Q. Below, no, in the darker blue.</p> <p>16 A. The dark blue, that's smaller</p> <p>17 arterial.</p> <p>18 Q. Those are blood vessels?</p> <p>19 A. Blood vessels, yes, larger blood</p> <p>20 vessels in terms of capillaries. It's larger</p> <p>21 than capillary.</p> <p>22 Q. Look at the bottom left corner of the</p> <p>23 picture. You see there's two -- these two brown</p> <p>24 or reddish dots?</p> <p>25 A. Yes.</p>	<p>1 an artifact.</p> <p>2 Q. Do nerves come in different shapes?</p> <p>3 A. Of course, they're all different. Not</p> <p>4 different as round and square, they're more</p> <p>5 rounded. But does that answer your question?</p> <p>6 Q. Yeah. That's fine.</p> <p>7 They obviously come in different</p> <p>8 sizes, too, depending upon where on the branch</p> <p>9 that you're looking at on the nerve?</p> <p>10 A. Yes.</p> <p>11 Q. And they can have a different</p> <p>12 appearance, depending upon how you section</p> <p>13 across the nerve?</p> <p>14 A. Yes.</p> <p>15 Q. So it's important to know the</p> <p>16 orientation of the nerve in the slide that</p> <p>17 you're looking at when it's cut, right?</p> <p>18 A. Yes. I mean the orientation will be</p> <p>19 -- of this cross-section will be different</p> <p>20 depending on the -- or shape of cross-section</p> <p>21 will be different depending on orientation.</p> <p>22 Q. Look at Figure 1c.</p> <p>23 A. Yes.</p> <p>24 Q. Now, this is a TVT-O mesh that's not</p> <p>25 from Mrs. Edwards, right?</p>

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<p>1 A. Yes. That's what it states, yes.</p> <p>2 Q. Who was it?</p> <p>3 A. I don't know. Another patient who had</p> <p>4 TVT-O explanted, TVT-O mesh explanted.</p> <p>5 Q. Would you have back at your office</p> <p>6 that patient's medical history, full medical</p> <p>7 history?</p> <p>8 A. I have to see what was this patient</p> <p>9 and what was -- what medical records I had</p> <p>10 available for that specific patient.</p> <p>11 Q. Do you know the orientation of the</p> <p>12 tissue that was processed for the pictures in</p> <p>13 Figure 1c?</p> <p>14 A. Orientation of the tissue, or</p> <p>15 orientation of the mesh?</p> <p>16 Q. Orientation of the tissue.</p> <p>17 A. I don't think I can -- well, how do</p> <p>18 you define "orientation of the tissue"? The</p> <p>19 mesh here, at least that part, was oriented the</p> <p>20 way that filaments were perpendicular to the</p> <p>21 sectioning plane, because I can see that it's</p> <p>22 almost rounded. Tissue orientation doesn't have</p> <p>23 landmarks, so you cannot define tissue</p> <p>24 orientation. Tissue itself has a landmark, so</p> <p>25 the longer access, shorter access.</p>	<p>1 describe this so we have --</p> <p>2 A. It's an acute angle. The nerve</p> <p>3 orientation along the long axis is at an acute</p> <p>4 angle to the sectioning plane.</p> <p>5 Q. And so for the record, you had your</p> <p>6 top hand essentially parallel with the table,</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the nerve is not under it directly</p> <p>10 parallel, but tilted up such that it would</p> <p>11 transverse the plane?</p> <p>12 A. Yes.</p> <p>13 Q. And it's at a significant angle,</p> <p>14 correct?</p> <p>15 A. It's an acute angle.</p> <p>16 Q. Acute. I couldn't remember your word.</p> <p>17 A. It's not 90 degrees. It's less than</p> <p>18 90 degrees.</p> <p>19 Q. So would you estimate 10 to</p> <p>20 15 degrees?</p> <p>21 A. Yeah, that's a reasonable estimate.</p> <p>22 One is -- has smaller -- the one on the right</p> <p>23 has smaller angle, and the one on the left has</p> <p>24 larger angle.</p> <p>25 Q. Do you know what the power was on</p>
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<p>1 Q. So what you're saying is because the</p> <p>2 mesh filaments appear to be pretty circular --</p> <p>3 A. Yes.</p> <p>4 Q. -- the mesh was oriented perpendicular</p> <p>5 to the way the cut was made?</p> <p>6 A. These specific filaments, they were</p> <p>7 oriented perpendicular. And as you can see in</p> <p>8 the blocks, the mesh is oriented perpendicular.</p> <p>9 Q. Okay. How were those nerves -- the</p> <p>10 brown staining, it's your opinion those are</p> <p>11 nerves?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And how were they oriented?</p> <p>14 A. These nerves (indicating)?</p> <p>15 Q. Yes.</p> <p>16 A. These are perpendicular to the</p> <p>17 filaments.</p> <p>18 Q. I think we're -- how was the nerve</p> <p>19 oriented in the tissue block at the time this</p> <p>20 cut was made?</p> <p>21 A. The nerves are at an acute angle to</p> <p>22 the tissue, to the sectioning plane, something</p> <p>23 like -- this is sectioning plane, this is a</p> <p>24 nerve (indicating).</p> <p>25 Q. Okay. Just so she -- we'll have to</p>	<p>1 Figure 1c?</p> <p>2 A. At least 25. The nerves are sizable.</p> <p>3 These nerves are almost as thick as the</p> <p>4 filament, so they're good nerves with good</p> <p>5 perineurium.</p> <p>6 Q. What does that mean?</p> <p>7 A. Nerves, when they get larger, they</p> <p>8 form specific sort of sheath of connective</p> <p>9 tissue, which is called perineurium. So you can</p> <p>10 go to nerves with perineurium, and then they</p> <p>11 slowly lose perineurium, they become thinner and</p> <p>12 thinner, and then taper down to small fibers</p> <p>13 which are called nerve twigs.</p> <p>14 Q. There's no mesh filaments on the</p> <p>15 outside of these nerves on Figure 1c, correct?</p> <p>16 A. I have to -- can you repeat the</p> <p>17 question?</p> <p>18 Q. Sure.</p> <p>19 There's no mesh filaments outside</p> <p>20 adjacent to these nerves in Figure 1c, correct?</p> <p>21 A. You mean on this side (indicating)?</p> <p>22 Q. On the opposite side of where --</p> <p>23 there's mesh filaments in-between the two</p> <p>24 nerves, correct?</p> <p>25 A. Yes.</p>

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<p>1 Q. But on the outside of those nerves, 2 there's no mesh filters? 3 A. I don't know. It's not in the 4 picture. Because see, this is .2-millimeter, 5 this is .2-millimeter, so this distance is less 6 than a millimeter. So if we check with the 7 largest span of the largest pores, the next set 8 of these filaments will be probably somewhere 9 here (indicating). So I would have to go and 10 check what was in the slide. 11 Q. Okay. Figure 2a, is this 12 Mrs. Edwards' mesh? 13 A. 2a, it doesn't state that it's 14 Ms. Edwards'. 15 Q. If you took pictures of Mrs. Edwards 16 and put them in your report, you would have 17 labeled them "Mrs. Edwards"? 18 A. Yes. 19 Q. You say here "Nerve entrapment and 20 deformation in an explanted TVT-O sling S100 21 stain, mesh filaments filled yellow in the lower 22 image copy." 23 In this case the mesh was curving 24 together with ingrown nerves, correct? 25 A. Yes.</p>	<p>1 A. I can only guess. 100 microns. 2 Q. How does the tissue get into that 3 area? 4 A. Grows in. 5 Q. Is that from the fibroblasts? 6 A. Fibroblasts included, to generate that 7 tissue, blood vessel need to be close by, then 8 fibroblasts need to come in, lay down collagen, 9 and the whole process. 10 Q. Turn to Figure 2b. 11 A. Yes. 12 Q. Do you know what power this was taken 13 at? 14 A. This is a low power. Most likely 2.5. 15 Q. And this isn't Mrs. Edwards' mesh 16 sling, correct? 17 A. No. Oh, actually that's here, the low 18 power of one of the images. That answers your 19 question. 20 So this mesh was migrating, so it 21 stretched the nerve. See the 2b lower? 22 Q. Yes. 23 A. This one, this part (indicating). 24 Q. Let me just put my glasses on. Go 25 ahead.</p>
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<p>1 Q. For the -- I take it your opinion is 2 that the brown in the middle is a nerve? 3 A. Yes. 4 Q. Okay. And then there's -- is that 5 tissue that's above and below it before you get 6 to the mesh filaments? 7 A. Yes. Everything is tissue here. 8 Q. What type of tissue is that which is 9 above and below the nerve? 10 A. Scar collagen. 11 Q. What are the blue dots? 12 A. Formatory cells, fibrocytes. 13 Q. And fibrocytes, what do they do? 14 A. Fibrocytes is a retired fibroblast. 15 Fibroblasts generate collagen, and then they 16 become inactive, and they become fibrocytes. 17 Q. And between the mesh filaments in the 18 bottom corner -- 19 A. You have to lift it up. 20 Q. I'm sorry. 21 The mesh filaments in the bottom 22 corner, there's also tissue in-between them? 23 A. Yes. 24 Q. What's the distance between those two 25 mesh pores?</p>	<p>1 A. See this part (indicating)? 2 Q. For the record, you're indicating the 3 upper right corner and you're now referencing 4 back to Figure 1c, correct? 5 A. Yes. 6 So this is a high power, this area, so 7 see this is very abnormal shape of a nerve. So 8 what happens -- and see, this mesh is also 9 folded, so it's a fold of the mesh, and then 10 mesh migrates in the tissue, and then stretch 11 the nerve here. So this is not ingrowth, but it 12 is deformation of the nerve by a migrating mesh 13 also deformed, because you can see it's curled 14 up like this (indicating). 15 Q. How is it curled? 16 A. Well, you see this one layer of mesh 17 and then this is the end of it. So it's like 18 that (indicating). 19 Q. How do you know that's not just the 20 plane in which the mesh was sectioned, such that 21 you're getting junctions of the mesh, or the 22 knitted -- 23 A. Well, it's either curled like this or 24 curled like that, because there is a second row, 25 at least one knot or intersection which is</p>

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<p>1 second. If it was one layer of a mesh, you 2 would have just this structure continue. If 3 there is anything beyond that, it either curled 4 like this, it then provided this filament, or 5 like that or like this. So there is a 6 deformation of the mesh (indicating). 7 Q. But this isn't Mrs. Edwards' mesh, 8 though, right? 9 A. No, no. It's a TVT-O sling, but it's 10 not Ms. Edwards'. 11 Q. And the brown areas on Figure 2b, it's 12 your opinion that those are nerves? 13 A. Yes. 14 Q. Now, down at the bottom of the picture 15 there's a whole bunch of nerves, correct? 16 A. Yes. 17 Q. That's your opinion, correct? 18 A. Yes. It's a very densely integrated 19 tissue, yes. 20 Q. There's no mesh adjacent to that, 21 correct? 22 A. At the end? 23 Q. Correct. 24 A. No, it's on here. 25 Q. Right.</p>	<p>1 ingrows into the mesh. 2 Q. Why are there nerves down in the 3 bottom corner -- strike that. 4 Why are there nerves in the bottom of 5 Figure 2b? In this area here I've circled. 6 A. Why there? 7 Q. Yes. 8 A. Because they just happened to be 9 there. They had -- 10 Q. Do you know whether those nerves were 11 there before? 12 A. Before the mesh placement? 13 Q. Yes. 14 A. Those exactly nerves below? 15 Q. Yes. 16 A. They could have been. Because they 17 are beyond the area which was created by the 18 mesh placement. 19 See, everything from here, from here 20 to there wasn't there before surgery. Or at 21 least anything, if we apply strict rules, 22 anything in-between here wasn't there before 23 surgery. 24 Now, if the mesh curled up during 25 surgery, this pocket was intra-operatively. If</p>
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<p>1 There's mesh up above it, correct? 2 A. Yes. 3 Q. But down there, there's nerves, and 4 there's no mesh around it? 5 A. In nerves are seen -- so this is mesh 6 which is curled either this way or that way, so 7 these nerves are trapped in the pocket of 8 deformation. These little guys in there are 9 within the mesh core. So this nerve is, as you 10 can see, between this, so the nerve apparently 11 had to make it all the way here, but then, 12 because it's a very unnatural way for a nerve to 13 connect to a target tissue, it's clear that the 14 mesh was migrating, deforming, and deforming in 15 an ingrown branch by the shape of all of this. 16 Q. How do you know that nerve wasn't 17 there before the mesh? 18 A. It's within the space of the mesh. 19 This tissue, this tissue didn't exist before the 20 mesh was placed. We started discussing before 21 lunch break the trocar damages tissue, creates a 22 cavity, and then mesh fills that cavity with its 23 own compartments, because mesh is 24 three-dimensional structure, and the blood fills 25 all these cavities of the mesh, and then tissue</p>	<p>1 the mesh migrated and curled up after surgery, 2 then this tissue could have been entrapped 3 during deformation. So it's hard to determine 4 if it was an intra-operative deformation or 5 later. But this corner, because it deforms 6 nerve, it migrated later. So I can say that by 7 this shape of the nerve, this migration happened 8 to be post-operatively. The nerves cannot grow 9 in almost like a 360 degrees circle. This is 10 really curled position (indicating). 11 Q. Are you saying that nerve in the top 12 right corner is the same nerve that's growing 13 around? 14 A. It could be. I don't know. 15 Q. So you're assuming that's the same 16 nerve? 17 A. It could be. 18 Q. You don't know? 19 A. I don't know for sure. 20 Q. Do you see some of the nerves in the 21 bottom here? 22 A. Both are deformed. Both segments -- 23 if it's the same nerve, it's one nerve deformed. 24 If it's two nerves, both, we will end up with 25 two deformed nerves.</p>

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<p style="text-align: right;">Page 246</p> <p>1 Q. The nerve down in the bottom away from 2 the mesh, did you count the density of those 3 nerves for that area and compare it to the nerve 4 density in the area within the mesh? 5 A. No, not for these specific samples. 6 Why it's not done? Because then some -- how 7 does mesh -- or how can mesh influence nerve 8 ingrowth or nerve regeneration by chemicals. So 9 if there are any chemical substances either 10 produced by mesh or by interaction of the mesh 11 with the body, your body produces some growth 12 factors when the mesh is placed, these chemicals 13 can spread over larger area, so it's not 14 scientific to limit your analysis here. You can 15 do this test, but arguably influence of the mesh 16 can stretch further up. So technically you 17 should measure everything which is in the tissue 18 which is changed. This tissue is changed. 19 There's collagen here. 20 Q. So now you're testifying that that 21 changed because of the mesh? 22 A. Collagen, the position in such a 23 density? 24 Q. The tissue at the bottom of this 25 picture.</p>	<p style="text-align: right;">Page 248</p> <p>1 nerve? 2 A. You have to point which blue dots. 3 Q. There's all different blue dots. 4 A. Mostly are inflammatory cells or 5 fibrocytes, or nuclei of inflammatory cells. 6 Q. This isn't a neuroma, correct? 7 A. No. Neuroma is the post-traumatic 8 deformation of nerve which appears as a 9 combination of deformed nerve and scar. 10 Q. Go to Figure 3a. Can you tell me 11 what's the power of this photo? 12 A. Probably 25. Maybe lower. Maybe 10. 13 Q. And that's tissue which is in-between 14 the mucosa and the mesh filaments? 15 A. Yes. 16 Q. Are nerves, is the mucosa made of -- 17 strike that. 18 Are there nerves in mucosa? 19 A. Nerve endings, but no nerves. There 20 is no nerves in the epithelium. 21 Q. You say "At this location, an external 22 pressure (intercourse) can compress the nerves 23 against the hardened mesh"? 24 A. Yes. 25 Q. Why did you say "can compress"?</p>
<p style="text-align: right;">Page 247</p> <p>1 A. At least part of it, yes, if this is 2 scar tissue. 3 Q. Is it scar tissue? 4 A. From this power it's hard to say, but 5 I mean it's light enough to be a scar tissue and 6 it's not adipose tissue. I would have to go 7 back and look at the slide to tell you exactly 8 if it's a scar or not. 9 But generally, scar tissue not just 10 fills the mesh, also extends beyond mesh, beyond 11 the mesh structures. There are four, if you 12 assess the scar, the scar affects area larger 13 than the mesh itself. 14 Q. Move to Figure 2c. What power was 15 this taken at? 16 A. This was with 40X. 17 Q. And your opinion is this shows central 18 degeneration? 19 A. It's demyelination. It's not 20 myelinated anymore. The central part of the 21 nerve is not myelinated. 22 Q. Is that a vessel directly above the 23 nerve? 24 A. Yes, a small one. 25 Q. And what are the blue dots around the</p>	<p style="text-align: right;">Page 249</p> <p>1 A. I guess it depends on the specific 2 intercourse movements, if there is direct 3 compression. Anything in the vagina can be 4 influenced or affected by intercourse, but 5 specific position can avoid pressure at specific 6 sites and can, I guess, have higher pressure 7 than other sites. 8 Q. Do you know if Mrs. Edwards complained 9 of pain with sex in the five years following her 10 mesh implantation? 11 A. I have to go back to the summary. If 12 there was dyspareunia, then she did. 13 Q. While you're looking, just so you 14 understand my question, it's a precise one -- 15 A. If she complained -- 16 Q. -- did Mrs. Edwards complain to her 17 doctors in the medical records in the five years 18 following her surgery when the TVT-O was 19 implanted? 20 MR. FABRY: Objection to the form. 21 The record speaks for itself. 22 A. I have to look, I don't remember where 23 she complained. I remember one of the 24 complaints with dyspareunia, or pain, but when 25 was it.</p>

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<p>1 You have to understand that I have</p> <p>2 multiple litigations with multiple patients, and</p> <p>3 I have my own 5,000 cases a year.</p> <p>4 (Witness reviewing document.)</p> <p>5 A. So the recorded complications which</p> <p>6 were recorded in 2011 included dyspareunia. So</p> <p>7 sometime between 2005 and 2011 she experienced</p> <p>8 dyspareunia. That's what was recorded.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. And it's your belief that was recorded</p> <p>11 in the records?</p> <p>12 A. I just copied whatever was in the</p> <p>13 records.</p> <p>14 Q. Okay. Turn to Figure 4a, jump over.</p> <p>15 A. Yes.</p> <p>16 Q. As well as 4b.</p> <p>17 These are not Mrs. Edwards, correct?</p> <p>18 A. No.</p> <p>19 Q. Are these TVT-O mesh?</p> <p>20 A. No.</p> <p>21 Q. And I think one of the things you</p> <p>22 pointed out here was there was a giant cell</p> <p>23 which you could see on this pathology slide?</p> <p>24 A. Yes.</p> <p>25 Q. And giant cells can form during part</p>	<p>1 A. There can be.</p> <p>2 Q. This myeloperoxidase stain --</p> <p>3 A. Yes.</p> <p>4 Q. -- the slide has colors of brown and</p> <p>5 blue. Which is the positive?</p> <p>6 A. Immunohistochemistry is positive when</p> <p>7 it's brown, because it gives the color. Blue is</p> <p>8 counterstain so you can see negative tissue.</p> <p>9 And blue is usually hematoxylin or some</p> <p>10 combination of hematoxylin and some other blue</p> <p>11 stain.</p> <p>12 Q. Figure 5, that's not Mrs. Edwards,</p> <p>13 correct?</p> <p>14 A. No.</p> <p>15 Q. Do you know what power these were</p> <p>16 taken at in Figure 5?</p> <p>17 A. Probably times 10.</p> <p>18 Q. Sorry?</p> <p>19 A. Times 10.</p> <p>20 Here you can see that this still</p> <p>21 remain filament, that's blue. And this one is</p> <p>22 crinkled, just an edge pulled off.</p> <p>23 Q. You note -- you write here, there's</p> <p>24 arrow legend that says "congested vessels."</p> <p>25 How do you know the status of that</p>
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<p>1 of the foreign body reaction?</p> <p>2 A. Yes.</p> <p>3 Q. Can giant cells form in the body even</p> <p>4 if a foreign body is not present?</p> <p>5 A. Yes.</p> <p>6 Q. When?</p> <p>7 A. There's a differential diagnosis for</p> <p>8 granulomatous inflammation. So giant cells, if</p> <p>9 we talk about macrophages in giant cells,</p> <p>10 because there are giant cells for other tissues,</p> <p>11 they are a hallmark of granulomatous</p> <p>12 inflammation. Or granulomatous inflammation is</p> <p>13 collection of epithelioid histiocytes, and this</p> <p>14 can include giant cells.</p> <p>15 So giant cells, macrophages, giant</p> <p>16 cells can be seen in granulomatous inflammation.</p> <p>17 Granulomatous inflammation can be seen as a</p> <p>18 reaction to foreign bodies, specific</p> <p>19 microorganisms, just necrotic debris of body,</p> <p>20 and some other obscure causes we don't know yet.</p> <p>21 Q. So if a surgery is done, let's say a</p> <p>22 mesh isn't put in, but a surgery is done and</p> <p>23 there's some necrotic tissue that results from</p> <p>24 that, can foreign body giant cells form to come</p> <p>25 in and try to clear out that debris?</p>	<p>1 vessel, and whether it was congested before mesh</p> <p>2 placement?</p> <p>3 A. Before placement?</p> <p>4 Q. Yes.</p> <p>5 A. Before placement that vessel didn't</p> <p>6 exist, because this vessel grew into the mesh</p> <p>7 structure. This is within the mesh.</p> <p>8 Q. Were there slides that you looked at</p> <p>9 pre and post-surgery that were able to discern</p> <p>10 what vessels were present and which ones were</p> <p>11 not?</p> <p>12 A. But this is common sense. I mean</p> <p>13 there is a space between filaments, and the</p> <p>14 space between filaments was introduced by</p> <p>15 placing mesh in the body. So, therefore,</p> <p>16 anything from here to there in this</p> <p>17 three-dimensional -- actually from here to</p> <p>18 there, because this is a film, anything from</p> <p>19 here to there is an ingrown tissue which has</p> <p>20 inhabited the mesh structure. You can get some</p> <p>21 sort of compression into this mesh structure,</p> <p>22 but you cannot fully fill all spaces.</p> <p>23 Q. Turn to Figure 6, Page 22.</p> <p>24 A. Yes.</p> <p>25 Q. Now, this is Mrs. Edwards' mesh?</p>

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<p>1 A. Yes.</p> <p>2 Q. Why did you take -- look at the top</p> <p>3 picture. Why did you take this photograph?</p> <p>4 A. Because it's thrombosed, it's</p> <p>5 thrombosed capillary.</p> <p>6 Q. There's not a legend or an arrow.</p> <p>7 Where is the thrombosed capillary in the top</p> <p>8 picture?</p> <p>9 A. The whole capillary. You can see</p> <p>10 in -- within the middle there's material which</p> <p>11 is degenerated. It means that there was a fiber</p> <p>12 and then it degenerated. This is not normal</p> <p>13 appearance of blood vessel. This substance is</p> <p>14 not normally seen in capillaries. This means</p> <p>15 that the circulation stopped (indicating).</p> <p>16 Q. You're pointing to the center part of</p> <p>17 the vessel and the bottom picture?</p> <p>18 A. This material and this material, this</p> <p>19 is not normal. And then this material, this is</p> <p>20 not normal (indicating). Normally you see</p> <p>21 erythrocytes and leukocytes in the capillaries.</p> <p>22 This is not normal content of blood vessel.</p> <p>23 Q. Was that important in your Edwards</p> <p>24 analysis?</p> <p>25 A. Yes. It means that circulation</p>	<p>1 And see this, these are lipocytes, and</p> <p>2 they're much smaller. And these areas here and</p> <p>3 there, there is fibrous tissue in-between them.</p> <p>4 This is a lipocyte, this is a lipocyte, here is</p> <p>5 fibrous tissue in-between. So these are full</p> <p>6 grown, and these are sort of sick lipocytes,</p> <p>7 they don't have enough fat (indicating).</p> <p>8 Q. Figures 8 and 9, those aren't</p> <p>9 Mrs. Edwards, correct?</p> <p>10 A. No.</p> <p>11 Q. No, they're not Mrs. Edwards?</p> <p>12 A. They are not Mrs. Edwards.</p> <p>13 Q. Is it your contention -- I'm looking</p> <p>14 at Figure 9, is it your opinion that when the</p> <p>15 surgeon excised this tissue that they excised</p> <p>16 part of the urethra?</p> <p>17 A. So some response can originate from</p> <p>18 vaginal wall urethral bladder. Vaginal wall has</p> <p>19 this wispy sort of appearance of the muscle.</p> <p>20 Urethra has more energized bundles and detrusor</p> <p>21 bundle muscle, they have bundles of muscle</p> <p>22 because they have to do a lot of work.</p> <p>23 So if you look at the specimen, this</p> <p>24 is interesting, see this side has this wispy</p> <p>25 muscle (indicating).</p>
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<p>1 stopped in that capillary -- in these two</p> <p>2 capillaries at least.</p> <p>3 Q. Is the photograph on the bottom a</p> <p>4 higher magnification of part of the top?</p> <p>5 A. No. These are two different.</p> <p>6 Q. Turn to Figure 7.</p> <p>7 Now, this isn't Mrs. Edwards, correct?</p> <p>8 A. No.</p> <p>9 Q. It is or --</p> <p>10 A. It is not.</p> <p>11 Q. What's the power of this Figure 7?</p> <p>12 A. Times 10, or 25. It's hard to say.</p> <p>13 Depends on how much it is cropped.</p> <p>14 Q. Now, in the middle there's fat</p> <p>15 deposition here, and they look like little</p> <p>16 circles.</p> <p>17 A. Yes.</p> <p>18 Q. Or oblong holes.</p> <p>19 A. Most of them are full circles, but</p> <p>20 some of them are in the generation process.</p> <p>21 They are pink. So normal fat is very</p> <p>22 homogeneous, round circles throughout. Once you</p> <p>23 have this collapse of adipose sites, they become</p> <p>24 pinker, because fat is gone out of them. So</p> <p>25 this is not healthy appearing fat.</p>	<p>1 Q. You're pointing to the left side?</p> <p>2 A. To the left side.</p> <p>3 And this side has bundles</p> <p>4 (indicating).</p> <p>5 Q. You're pointing to the right side?</p> <p>6 A. To the right side.</p> <p>7 So see the curve? So this was peeled</p> <p>8 off the urethra. So some of this muscle is</p> <p>9 probably stripped from the vaginal wall, some</p> <p>10 was from the urethra. So during dissection it</p> <p>11 appears that some of the urethral muscle was</p> <p>12 removed.</p> <p>13 Q. Figure 10a, obviously this is not</p> <p>14 Mrs. Edwards, correct?</p> <p>15 A. No.</p> <p>16 Q. Do you know what brand this is in 10a?</p> <p>17 A. Probably Boston Scientific. It's a</p> <p>18 thicker mesh. They use thicker mesh for</p> <p>19 prolapse devices.</p> <p>20 Q. In Mrs. Edwards' specimens you didn't</p> <p>21 see bladder wall, correct?</p> <p>22 A. No. It's transvaginal placement. But</p> <p>23 I guess they can migrate. Sorry. I did not see</p> <p>24 bladder wall in Ms. Edwards' specimen.</p> <p>25 Q. Did you see urethra wall in</p>

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<p>1 Mrs. Edwards' specimen?</p> <p>2 A. I have to go and check with the</p> <p>3 pictures.</p> <p>4 I think you asked about this. I</p> <p>5 probably missed that statement. I think I</p> <p>6 recognize this picture.</p> <p>7 Q. Which one are you looking at, Doctor,</p> <p>8 just so we know?</p> <p>9 A. TE4a.</p> <p>10 Q. You're on Page 61 of your expert</p> <p>11 report?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Go ahead.</p> <p>14 A. So this is labeled Mrs. Edwards</p> <p>15 specimen. And I think in the first part of the</p> <p>16 expert report this picture was not labeled as</p> <p>17 her specimen. It appears that I missed the</p> <p>18 labelling.</p> <p>19 So on Page 24 --</p> <p>20 Q. Okay.</p> <p>21 A. -- the lower images are for</p> <p>22 Ms. Edwards, at least lower images.</p> <p>23 Q. How do you know which one is correct?</p> <p>24 How do you know whether or not it came from</p> <p>25 Mrs. Edwards?</p>	<p>1 Q. So TE -- let's look at Figure TE5, the</p> <p>2 thrombosed capillaries. That's the same as</p> <p>3 Figure 6 which we looked at earlier on Page 22?</p> <p>4 A. Yes.</p> <p>5 Q. And that's Mrs. Edwards' mesh?</p> <p>6 A. Yes.</p> <p>7 Q. So in Figure 9, is that mislabeled?</p> <p>8 A. Figure 9, just 9?</p> <p>9 Q. Yes.</p> <p>10 A. Yeah, I didn't provide this</p> <p>11 information that it was Ms. Edwards. Because I</p> <p>12 was providing this picture later on, I thought</p> <p>13 that --</p> <p>14 Q. Turn to Page 28, Figure 12.</p> <p>15 A. Yes.</p> <p>16 Q. Okay. This is Mrs. Edwards' specimen?</p> <p>17 A. Yes.</p> <p>18 Q. We talked about the process of how the</p> <p>19 mesh came to get to this point, correct?</p> <p>20 A. Yes.</p> <p>21 Q. Is this a photo you took?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And what's the liquid that's in</p> <p>24 the background below the specimen on Figure 12?</p> <p>25 A. Just formalin draining from the</p>
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<p>1 A. Because this was specifically selected</p> <p>2 and saved in a folder specifically for</p> <p>3 Ms. Edwards. I was taking pictures at one time,</p> <p>4 loading the same memory card, so there's no way</p> <p>5 of mixing them up.</p> <p>6 Q. And you have that memory card, or you</p> <p>7 have those folders in your computer?</p> <p>8 A. I save them, yes.</p> <p>9 So we were talking about bladder wall.</p> <p>10 No, I did not see bladder wall.</p> <p>11 Q. You didn't see urethral wall either in</p> <p>12 Mrs. Edwards' case?</p> <p>13 A. TE4b, Page 62, the bundles on the</p> <p>14 right, they're too thick to be just vaginal</p> <p>15 wall. Also the curving. So the curvature</p> <p>16 around the urethra, this is wispy muscle in the</p> <p>17 vaginal wall, these are bundles. You can</p> <p>18 appreciate the difference, thicker bundles</p> <p>19 towards urethral side, thinner wisps on the</p> <p>20 vaginal wall (indicating).</p> <p>21 Q. So it's your -- just so I understand,</p> <p>22 it's your contention that TE4b is actually from</p> <p>23 Mrs. Edwards?</p> <p>24 A. Yes. All images labeled "TE" are from</p> <p>25 Mrs. Edwards.</p>	<p>1 specimen.</p> <p>2 Q. So this would have been after you took</p> <p>3 it out of formalin, but before it went through</p> <p>4 the process to get into paraffin that we talked</p> <p>5 about?</p> <p>6 A. Yes.</p> <p>7 Q. And that was the entirety of the</p> <p>8 specimen that was in the formalin?</p> <p>9 A. Yes.</p> <p>10 Q. Figure 13a, can you tell me the power</p> <p>11 on that?</p> <p>12 A. Very low. Either times 1 or times</p> <p>13 2.5.</p> <p>14 Q. Can you tell me the angle in which the</p> <p>15 microtome cut that tissue specimen?</p> <p>16 A. You mean mesh?</p> <p>17 Q. Well, I mean the tissue specimen.</p> <p>18 A. Tissue orientation, tissue -- if it</p> <p>19 doesn't have landmark specific, it doesn't</p> <p>20 have -- because tissue around the mesh is sort</p> <p>21 of about the same dimension. But the mesh can</p> <p>22 vary if it is flat. If it's round it's</p> <p>23 difficult to rend, because any way you turn it's</p> <p>24 -- some parts will be angled, some parts will be</p> <p>25 perpendicular.</p>

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<p>1 Q. Do you know how this mesh was oriented</p> <p>2 in this photograph?</p> <p>3 A. It was oriented, you can see in the</p> <p>4 block, perpendicular, because you see</p> <p>5 cross-sections. So this part of the mesh is</p> <p>6 perpendicular. This part has a complex</p> <p>7 orientation because some filaments are</p> <p>8 perpendicular, some filaments are clearly</p> <p>9 parallel. Like this filament is almost</p> <p>10 parallel. So either mesh curled like this, or</p> <p>11 it curled like this. But in any case it's not a</p> <p>12 flat structure anymore (indicating).</p> <p>13 Q. It's how you put it into the paraffin</p> <p>14 block, correct?</p> <p>15 A. I can only orient what is there. So</p> <p>16 if it's deformed, then choose to see if it's</p> <p>17 mostly on edge. In this case, this tail, or</p> <p>18 this further part is on edge perpendicular. But</p> <p>19 this one, any way you turn, there's no edge.</p> <p>20 Q. And that's because that's the way that</p> <p>21 specimen was put into the paraffin?</p> <p>22 A. No. Because it deformed in the body.</p> <p>23 Q. How did it deform in the body when</p> <p>24 you're looking at Figure 28? Strike that.</p> <p>25 How does Figure 12 match up to Figure</p>	<p>1 samples processed?</p> <p>2 MR. FABRY: Objection to form.</p> <p>3 A. If it is fused by scar tissue, the</p> <p>4 deformation was fused in vivo.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. You're saying "if." Was it?</p> <p>7 A. It is.</p> <p>8 Q. Okay. So --</p> <p>9 A. It's in the pictures. All spaces are</p> <p>10 filled by scar tissue. The shape is fused by</p> <p>11 scar tissue, scar tissue is mature, it occurred</p> <p>12 months before explantation.</p> <p>13 Q. So it's your opinion, then, that the</p> <p>14 way that you had Mrs. Edwards' mesh fixed in</p> <p>15 paraffin had no influence on that photograph,</p> <p>16 correct?</p> <p>17 MR. FABRY: Objection to form.</p> <p>18 A. On the shape of the mesh?</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Yes.</p> <p>21 A. It did not cause the deformation,</p> <p>22 because the deformation is fused by scar.</p> <p>23 Processing doesn't cause scar to appear in the</p> <p>24 spaces.</p> <p>25 Q. Turn to Page 14, and tell me what the</p>
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<p>1 13?</p> <p>2 A. One of the pieces is here. So one of</p> <p>3 the pieces there is this, or that, or this one</p> <p>4 is here. So if you can see that this end seems</p> <p>5 to be flat, but we don't know what's going on</p> <p>6 there. So mesh goes like this and then curls at</p> <p>7 the end, creating this structure (indicating).</p> <p>8 Q. Is it your opinion that Mrs. Edwards'</p> <p>9 mesh was curled?</p> <p>10 A. Yes. It's here in the picture. This</p> <p>11 is deformed mesh. It's not flat. This is the</p> <p>12 same mesh. One part is sectioned like this, but</p> <p>13 then suddenly there are more structures in</p> <p>14 there. If it was one mesh, one flat plane, it</p> <p>15 would just continue, and you wouldn't see that</p> <p>16 part of the image at all. This would be all</p> <p>17 filled like this. So this end, is it curled</p> <p>18 like this, or curled like that? But this end is</p> <p>19 deformed. Because there is no other way to</p> <p>20 produce this orientation other than to deform a</p> <p>21 mesh (indicating).</p> <p>22 Q. So it's your opinion that that type of</p> <p>23 orientation can't occur during the mesh sitting</p> <p>24 in the formalin for a year plus of time, and it</p> <p>25 can't occur based upon the way that you had the</p>	<p>1 power of this photo is. Figure 14.</p> <p>2 A. Figure 14.</p> <p>3 Q. I'm sorry.</p> <p>4 A. Page 14.</p> <p>5 Q. Let me just ask a plain question.</p> <p>6 On Page 31, we're looking at Figure</p> <p>7 14, can you tell me the power of those two</p> <p>8 photographs?</p> <p>9 A. This is very low, either 1 or 2.5. I</p> <p>10 think 1.</p> <p>11 Q. This isn't Mrs. Edwards' mesh,</p> <p>12 correct?</p> <p>13 A. No.</p> <p>14 Q. No, it's not Mrs. Edwards'?</p> <p>15 A. It's not. I mean if you ask if it is</p> <p>16 or isn't, it's easier for me to -- not easy.</p> <p>17 Okay. It's not Ms. Edwards.</p> <p>18 Q. Okay. Mrs. Edwards didn't have an</p> <p>19 infection, correct?</p> <p>20 MR. FABRY: Objection. Form.</p> <p>21 A. I don't know that. I did not see</p> <p>22 acute inflammation in the monitor firmly stated</p> <p>23 that there was bacterial infection, but</p> <p>24 subclinical amount of infection could be there.</p> <p>25 BY MR. SNELL:</p>

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<p>1 Q. You did not see pathologic evidence of</p> <p>2 an infection?</p> <p>3 A. I did not see morphologic evidence of</p> <p>4 bacterial infection sufficient to be detected by</p> <p>5 histological means. Gold standard for infection</p> <p>6 is cultures.</p> <p>7 Q. Cultures done turned up positive in</p> <p>8 Mrs. Edwards' case that you saw?</p> <p>9 A. I don't know.</p> <p>10 Q. Did you ask for them?</p> <p>11 A. No.</p> <p>12 Q. So you don't know whether -- based on</p> <p>13 everything you reviewed, you have not seen</p> <p>14 evidence of infection in Mrs. Edwards' case,</p> <p>15 correct?</p> <p>16 A. No. But it doesn't mean that it</p> <p>17 wasn't there. As I said, I'm a pathologist,</p> <p>18 pathologists detecting -- can detect only</p> <p>19 specific infections. But gold standard for</p> <p>20 infection is microbiology, and this has to be</p> <p>21 done at the time of surgery.</p> <p>22 Q. Okay. And in Mrs. Edwards' case, did</p> <p>23 you see an abscess in the pathology?</p> <p>24 A. No, I don't believe there was an</p> <p>25 abscess.</p>	<p>1 acute inflammation, that I did not see. But you</p> <p>2 need large amount of bacteria in the area to</p> <p>3 produce acute inflammation.</p> <p>4 Q. You didn't see large amounts of acute</p> <p>5 inflammation in Mrs. Edwards' case?</p> <p>6 A. No.</p> <p>7 Q. Turn to Page 32, Figure 15.</p> <p>8 A. Yes.</p> <p>9 Q. This is not an Ethicon mesh, correct?</p> <p>10 A. No.</p> <p>11 Q. I'm sorry, we just -- is it an Ethicon</p> <p>12 mesh, Figure 15?</p> <p>13 A. It is not Ethicon mesh.</p> <p>14 Q. All right.</p> <p>15 MR. FABRY: Can we take a short break?</p> <p>16 MR. SNELL: Absolutely.</p> <p>17 (Whereupon, a recess was taken from</p> <p>18 3:25 p.m. to 3:33 p.m.)</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Doctor, let's go to Figure 16a, the</p> <p>21 new TVT-O mesh.</p> <p>22 This is the mesh that you stretched,</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 Q. Where is the mesh sheath?</p>
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<p>1 Q. Figure 15, Page 32.</p> <p>2 A. Actually, yes, I didn't see abscess,</p> <p>3 but I think she had mesh exposure at the time of</p> <p>4 surgery. So I can state that because it was</p> <p>5 exposed, there was infection in there. It just</p> <p>6 didn't produce enough acute inflammation.</p> <p>7 Because if there is exposure of anything of the</p> <p>8 external surface, it is infected.</p> <p>9 Q. How is it infected?</p> <p>10 A. Anything on the surface is infected.</p> <p>11 It can be infected inside, but on the surface,</p> <p>12 definitely infected.</p> <p>13 Q. So what you're testifying to is that</p> <p>14 there are bacteria on the surface following an</p> <p>15 exposure?</p> <p>16 A. There is bacteria always on the</p> <p>17 surface. Any external surfaces of our body or</p> <p>18 communicating with external surface have</p> <p>19 bacteria. Bacteria can also be present inside,</p> <p>20 but on the surface they're always present.</p> <p>21 Q. But from everything you've looked at,</p> <p>22 there was no active infection that showed up in</p> <p>23 any cultures, correct?</p> <p>24 A. I didn't do cultures. What I can see</p> <p>25 if there is enough bacterial infection to cause</p>	<p>1 A. It's removed.</p> <p>2 Q. Did you remove the mesh sheath before</p> <p>3 or after you stretched it?</p> <p>4 A. Before.</p> <p>5 Q. And you stretched it for five minutes</p> <p>6 statically?</p> <p>7 A. Yes.</p> <p>8 Q. What does that mean; you put a</p> <p>9 continuous stretch on it for five minutes?</p> <p>10 A. Yeah. The clamps were fixed in</p> <p>11 specific lengths.</p> <p>12 Q. What type of clamps did you use for</p> <p>13 this test?</p> <p>14 A. Hemostatic clamps.</p> <p>15 Q. So you oriented the hemostatic clamps</p> <p>16 on the ends of the mesh and pulled it?</p> <p>17 A. Yes.</p> <p>18 Q. Did you measure the Newtons or force</p> <p>19 in which you pulled it?</p> <p>20 A. No.</p> <p>21 Q. Were there any ANSI approved test</p> <p>22 methods that you used?</p> <p>23 A. No. This is not an industry grade</p> <p>24 test. This is a test I would do just on a live</p> <p>25 device and what it can do in the body. That's</p>

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<p>1 my observational sort of testing as I would</p> <p>2 normally do with other implantable devices if I</p> <p>3 have questions.</p> <p>4 Q. Have you ever looked at the TVT-O</p> <p>5 instructions for use?</p> <p>6 A. Yes.</p> <p>7 Q. Do they describe doing any type of</p> <p>8 pulling, like you did your test here with the</p> <p>9 sheath hole?</p> <p>10 A. No. But the pulling is not simulated</p> <p>11 to insertion procedure. The pulling is</p> <p>12 simulated to the processes which happened in the</p> <p>13 body.</p> <p>14 Q. Looking at the bottom left photograph.</p> <p>15 A. Yes.</p> <p>16 Q. Did you stand that mesh up on end?</p> <p>17 A. I wouldn't lay flat. I would have to</p> <p>18 flatten it for the lower right. But after the</p> <p>19 stretch, it curls up. This is free shape it</p> <p>20 assumed after the stretching. After the</p> <p>21 pressure was released, it curled up, and then it</p> <p>22 couldn't lay flat.</p> <p>23 Q. What I'm asking is for the bottom left</p> <p>24 corner photograph, did you turn the mesh up on</p> <p>25 its end, on its edge?</p>	<p>1 essentially similar to the way it was before?</p> <p>2 MR. FABRY: Objection. Form.</p> <p>3 A. Similar, that's a questionable. I</p> <p>4 mean the length has changed, therefore they're</p> <p>5 flattened.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. Are the pores larger, smaller, or how</p> <p>8 do they compare -- strike that.</p> <p>9 How do the pores in the bottom right</p> <p>10 picture compare to the pores in the top right</p> <p>11 picture?</p> <p>12 A. They are deformed.</p> <p>13 Q. How?</p> <p>14 A. Stretched.</p> <p>15 Q. What's the distance difference between</p> <p>16 the top right and the top left photographs in</p> <p>17 the mesh pores?</p> <p>18 A. 10 percent. So 5 millimeters out of 5</p> <p>19 centimeters is 10 percent. So the length of the</p> <p>20 pores in the whole mesh is 10 percent larger</p> <p>21 than before the test.</p> <p>22 Q. So after you submitted the mesh to</p> <p>23 this test, the length of the pores was 10</p> <p>24 percent longer?</p> <p>25 A. Yes. Along the stretched pores.</p>
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<p>1 A. It did it itself.</p> <p>2 Q. Okay. And you can see through the</p> <p>3 mesh?</p> <p>4 A. Yes.</p> <p>5 Q. What's the white background?</p> <p>6 A. Paper. A sheet of paper.</p> <p>7 Q. Okay. And that's a millimeter ruler</p> <p>8 you have next to the mesh in the bottom right</p> <p>9 corner?</p> <p>10 A. Yes. It shows you that the mesh was 5</p> <p>11 centimeters, these marks, and stretched to six</p> <p>12 centimeters, 120 percent of original length.</p> <p>13 And then the force was released, it curled up.</p> <p>14 And then I had to flatten it, and measured the</p> <p>15 length between the marks, and it wasn't original</p> <p>16 5 centimeters, it wasn't six centimeters, it</p> <p>17 returned somewhat close to original length, but</p> <p>18 it didn't really return to original length.</p> <p>19 Q. The bottom right corner which shows</p> <p>20 the mesh next to the ruler, you can still see</p> <p>21 through those pores?</p> <p>22 A. Yes.</p> <p>23 Q. Those pores are still intact?</p> <p>24 A. What is definition of intact pore?</p> <p>25 Q. The geometry of the pores is</p>	<p>1 Q. And the width, was it about the same,</p> <p>2 or did you even measure that?</p> <p>3 A. I don't know. I didn't measure that.</p> <p>4 It was smaller, but I didn't measure exactly by</p> <p>5 how much.</p> <p>6 Q. Was this a mesh that was exposed to</p> <p>7 paraffin or any chemicals?</p> <p>8 A. No, not this one. I exposed it to</p> <p>9 formalin later, not before the test.</p> <p>10 Q. And is this a test that you came up</p> <p>11 with that's depicted in Figure 16a?</p> <p>12 A. Yes. I had new meshes and I saw the</p> <p>13 curling of the meshes, of explanted meshes. And</p> <p>14 when I had new meshes, tried to simulate what</p> <p>15 happens, and what happens sling is being placed</p> <p>16 to support the urethra. So the whole idea is it</p> <p>17 applies some pressure on the urethra. So its</p> <p>18 counterforce would be stretching. So this</p> <p>19 stretching is a simulation of what happens</p> <p>20 in vivo.</p> <p>21 Q. In your test you applied positive</p> <p>22 forces on the ends of the mesh and pulled it</p> <p>23 laterally?</p> <p>24 A. Yes.</p> <p>25 Q. With constant force?</p>

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<p>1 A. Yes.</p> <p>2 Q. Do you know that TVT is implanted</p> <p>3 without fixation?</p> <p>4 A. There is no stitching. It's implanted</p> <p>5 without stretching. But then it grows in, so</p> <p>6 the tissue incorporation fixes the ends.</p> <p>7 Q. The growth -- the tissue grows into</p> <p>8 the mesh?</p> <p>9 A. Yes.</p> <p>10 Q. But TVT mesh is not sutured, correct?</p> <p>11 A. No. As far as I understand, no.</p> <p>12 Q. As far as you understand, the TVT mesh</p> <p>13 is not sutured?</p> <p>14 A. Yes. As far as I understand, the TVT</p> <p>15 mesh is not sutured.</p> <p>16 Q. Okay. Figure 18a, is that a picture</p> <p>17 from Mrs. Edwards?</p> <p>18 A. No, it's not.</p> <p>19 Q. Is that an Ethicon mesh?</p> <p>20 A. No.</p> <p>21 Q. Figure 18 and Figure 19, are those</p> <p>22 photographs of an Ethicon mesh?</p> <p>23 A. No.</p> <p>24 Q. And are those photographs -- are</p> <p>25 Figures 18 and 19 photographs of Mrs. Edwards'</p>	<p>1 specimen without a bark. Maybe if it's removed</p> <p>2 very early it's not detectable. But all</p> <p>3 specimens came to me with at least a one year</p> <p>4 exposure, so inflammation, no inflammation, it's</p> <p>5 still there.</p> <p>6 Q. Figures 20, 21, 22, 23, are those</p> <p>7 TVT-O meshes?</p> <p>8 A. 20.</p> <p>9 21, no. 21, no, it's not TVT. I did</p> <p>10 section TVT meshes, just a quality, but I did</p> <p>11 experiment with this. If I section further in</p> <p>12 the block I can produce better quality slides of</p> <p>13 formalin-exposed TVT-O mesh.</p> <p>14 Q. Figure 22 says "New mesh of the same</p> <p>15 brand." Is that referring back to the meshes in</p> <p>16 Figure 20?</p> <p>17 A. Yes. So this was perfect set. Brand</p> <p>18 new mesh, no new exposure to formalin. By now I</p> <p>19 have the same mesh with one month exposure to</p> <p>20 formalin as a control, then a patient with one</p> <p>21 year of in vivo exposure, and then patient with</p> <p>22 nine years of in vivo exposure, no bark, very</p> <p>23 thin bark, much thicker bark.</p> <p>24 Q. Did you measure the thickness of the</p> <p>25 bark to determine whether there was a</p>
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<p>1 mesh?</p> <p>2 A. No. This was interesting observation,</p> <p>3 because both belong to the same brand.</p> <p>4 Q. Do you know what brand it was?</p> <p>5 A. I believe AMS. And they were exposed</p> <p>6 to different length in vivo, therefore I could</p> <p>7 compare degradation bark.</p> <p>8 Q. Have you seen any published scientific</p> <p>9 literature that describes a degradation bark?</p> <p>10 A. In polypropylene?</p> <p>11 Q. Yes.</p> <p>12 A. No. That's the problem, it's been</p> <p>13 around for 50 years and nobody detected it. At</p> <p>14 least nobody detected it in cross-sections in</p> <p>15 microscopy.</p> <p>16 Q. The use of the word "bark," that is</p> <p>17 not a pathologic term, correct?</p> <p>18 A. It's a descriptive term. That's how</p> <p>19 it looks. In pathology there are many words</p> <p>20 from food. Nutmeg lever is a pathological term.</p> <p>21 Q. In Figures 18, 18b, this area by the</p> <p>22 bark, as you call it, is there increased</p> <p>23 inflammation at that area?</p> <p>24 A. No. The bark is in each specimen,</p> <p>25 each explanted mesh. I have not seen a single</p>	<p>1 statistically significant difference in that</p> <p>2 thickness as compared amongst those years?</p> <p>3 A. This bark was 1 to 2 microns, this</p> <p>4 bark was 4 to 5 microns.</p> <p>5 Q. Did you calculate whether that was</p> <p>6 statistically significant? Strike that. Let me</p> <p>7 just -- that was a bad question.</p> <p>8 Did you perform a calculation to</p> <p>9 determine whether that difference in thickness</p> <p>10 of the bark that you claim is in those</p> <p>11 photographs was a statistically significant</p> <p>12 difference based on the samples?</p> <p>13 MR. FABRY: Objection. Form.</p> <p>14 A. Within these two, no. It's a project</p> <p>15 to perform. But at this stage, it was uniformly</p> <p>16 2 microns. I have never seen taken any</p> <p>17 measurement from this patient more than 2</p> <p>18 microns. I can do statistical tests. But if</p> <p>19 you have all numbers, smaller or larger,</p> <p>20 statistical tests will be significant, because I</p> <p>21 know that there's a researcher.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. When you only have a limited number of</p> <p>24 samples, statistical significance isn't</p> <p>25 guaranteed, even though there may be a numerical</p>

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<p>1 difference. You know that as a scientist, 2 correct? 3 A. But you can measure. 4 Q. No, you have no answer my question 5 first. 6 You know as a scientist that when you 7 have a low number of samples that you are 8 analyzing and looking at to see whether there is 9 a statistically significant difference, just 10 because there is a numerical difference does not 11 necessarily mean there is a statistically 12 significant difference; do you agree or disagree 13 with that? 14 MR. FABRY: Can I just interpose an 15 objection to the misuse of the term "statistical 16 significance" as to this hypothetical. 17 And you can go ahead and answer. 18 BY MR. SNELL: 19 Q. Do you agree or disagree? 20 A. Data points, not samples. The same 21 sample can be measured at different parts to 22 create data points. Multiple data points can be 23 put into statistical tests. 24 So if I measure barkness in different 25 filaments from the same sample, this will create</p>	<p>1 test, it's not that hard to do -- but I know as 2 a researcher that it will be indefinitely -- the 3 p-value will be indefinitely small. 4 Q. So what is the mean width then of the 5 bark for the longer exposed meshes? 6 A. 4 microns. 7 Q. All right. And what is the confidence 8 interval, 95 percent confidence interval? 9 A. Didn't do that. 10 You mean for that specific mesh that I 11 was measuring? 12 Q. Yes. 13 A. I didn't calculate confidence 14 interval. But it wasn't reaching 2 microns of 15 the other. 16 Q. Turn, if you would, to -- let me just 17 make a request on the record. Request for 18 production of your pathology report in the 19 Edwards case. 20 How many pages is it? 21 A. Two pages, one page. 22 MR. FABRY: I'm pretty sure it's two. 23 As certain as I can be, at some point it must 24 have been produced to you. But -- 25 MR. SNELL: It's not attached to his</p>
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<p>1 a large data set. Then it will reach 2 statistical significance. 3 Q. You haven't done that, though? 4 A. I've done that. I measured filaments, 5 different filaments. 6 Q. Where are your calculations showing 7 that this is statistically significant 8 different? 9 A. I didn't test, because all of these 10 measurements were within 2-micron tests. 11 There's no point of doing statistical tests, the 12 p-value will be indefinitely small. Because 13 data sets I measured were completely separate, 14 there were no overlap. There's no point of 15 doing statistical tests. 16 Everything is between 1 and 2, 17 everything here is between 4 and 5, no overlap. 18 You do statistical tests to see if the overlap 19 completely overlaps both data sets, or there is 20 a small overlap, therefore you calculate the 21 width of the overlap. If it's 5 percent or 22 less, it becomes that the difference is 23 95 percent -- is present to 95 percent 24 certainty. 25 If there's no overlap -- I can do this</p>	<p>1 report, and it's never been produced to me, so I 2 don't have it. If I had it, I would mark it, 3 because I'd like to mark it and ask you about 4 it. 5 MR. FABRY: I didn't bring it. 6 Can we go off the record for a second? 7 BY MR. SNELL: 8 Q. Did you make a report in Mrs. Huskey's 9 case? 10 A. Are we -- 11 Q. We're on the record. 12 MR. FABRY: Okay. Do you want to deal 13 with getting the pathology report that you were 14 just asking about? Or do you want to forget 15 about that and move on to something else? 16 MR. SNELL: I'm not forgetting about 17 it. 18 BY MR. SNELL: 19 Q. I just want to know, before I 20 transition to something else, I want to know did 21 you generate a pathology report for the Huskey 22 case? 23 A. No, I didn't have a specimen. 24 MR. SNELL: Okay. All right. If you 25 have the report, I'd like it.</p>

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<p>1 MR. FABRY: We're working on getting</p> <p>2 it for you right now. I agree, it didn't seem</p> <p>3 to come with the copy of the expert report that</p> <p>4 I received. But I have seen it, and it was my</p> <p>5 sincere belief that at some point --</p> <p>6 MS. THOMPSON: It should have been</p> <p>7 attached. It was an oversight, I believe.</p> <p>8 MR. FABRY: Okay.</p> <p>9 MR. SNOWDEN: So it wasn't produced</p> <p>10 then?</p> <p>11 MR. FABRY: I'm not saying that.</p> <p>12 MR. SNOWDEN: If it was an oversight</p> <p>13 and not attached it, wasn't produced.</p> <p>14 MR. FABRY: It's oversight.</p> <p>15 MR. SNOWDEN: I'm trying to</p> <p>16 understand.</p> <p>17 MR. FABRY: What she's saying is as</p> <p>18 far as we can tell it was not attached to this</p> <p>19 report.</p> <p>20 MR. SNOWDEN: That you brought with</p> <p>21 you today?</p> <p>22 MR. FABRY: That was produced as the</p> <p>23 Rule 26 report.</p> <p>24 MR. SNOWDEN: Okay.</p> <p>25 MR. FABRY: What I'm saying is it has</p>	<p>1 into areas that are as small as 500 nanometers</p> <p>2 wide?</p> <p>3 A. At least they can stick to</p> <p>4 pseudopodia.</p> <p>5 Q. Well, this cell you have a picture of</p> <p>6 here which you say wedged into the crack, what's</p> <p>7 the width of that crack?</p> <p>8 A. About 600 nanometers. Or in the</p> <p>9 width, the widest part is about 600 nanometers.</p> <p>10 Q. Okay. And 1,000 nanometers equals 1</p> <p>11 micron, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Is that correct?</p> <p>14 A. Yes.</p> <p>15 Q. For Mrs. Edwards, did you look at all</p> <p>16 of her medical records between the time of her</p> <p>17 TVT-O implantation up until the time of when she</p> <p>18 presented for explantation to see what were her</p> <p>19 symptoms and complaints during that six and a</p> <p>20 half year period?</p> <p>21 A. No. As I mentioned, as a pathologist</p> <p>22 I extract only the information which is relevant</p> <p>23 to the specimen I examine, so I'm very</p> <p>24 selective. Specifically I check what was time</p> <p>25 of insertion, and records describing change of</p>
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<p>1 been my belief that it was separately and</p> <p>2 otherwise produced to you in the litigation.</p> <p>3 But as I'm sitting here right now, I can't</p> <p>4 answer the question, you know, where it went.</p> <p>5 We're always a little bit relying on what other</p> <p>6 folks are telling us.</p> <p>7 MR. SNOWDEN: I'm making sure we're</p> <p>8 all on the same page.</p> <p>9 MR. FABRY: None of that was supposed</p> <p>10 to be on the record.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. Let's go to Figure 28. You said</p> <p>13 there's a cell wedged in a crack in a</p> <p>14 non-Ethicon transobturator sling?</p> <p>15 A. Yes.</p> <p>16 Q. What type of cell is that?</p> <p>17 A. Most likely macrophage.</p> <p>18 Q. And how did the macrophage get into</p> <p>19 this non-Ethicon transobturator sling space?</p> <p>20 A. You told me yourself the inflammatory</p> <p>21 cells squeeze into small spaces to deliver their</p> <p>22 function.</p> <p>23 Q. I can't testify.</p> <p>24 Is that what your opinion is, the</p> <p>25 inflammatory cells like macrophages can squeeze</p>	<p>1 symptoms that appear after insertion, or</p> <p>2 symptoms which led to excision, and then records</p> <p>3 of the excision and after excision. I'm reliant</p> <p>4 on clinical work-up of the differential</p> <p>5 diagnosis.</p> <p>6 (Whereupon, Iakovlev Exhibit Number 8,</p> <p>7 Pathology report in Ms. Edwards' case,</p> <p>8 was marked for identification.)</p> <p>9 BY MR. SNELL:</p> <p>10 Q. Exhibit 8 I've just handed you is a</p> <p>11 pathology report in Mrs. Edwards' case.</p> <p>12 A. Yes.</p> <p>13 Q. You've seen this document before, or</p> <p>14 have you not?</p> <p>15 A. Probably I did. Was it the same date?</p> <p>16 Probably I did, because if it's the same</p> <p>17 specimen, it usually comes with the specimen.</p> <p>18 Q. You see at the top it says "Soft</p> <p>19 tissue with chronic inflammation and focal</p> <p>20 foreign body giant cell reaction"?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know whether or not you</p> <p>23 actually reviewed this report prior to today?</p> <p>24 A. If my pathology report indicates that</p> <p>25 there is accompanying pathology report, then I</p>

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<p>1 did, because I always record if there's</p> <p>2 pathology report accompanies the specimen.</p> <p>3 Q. The pathology report does not state</p> <p>4 that there was any mesh exposure, correct?</p> <p>5 A. It actually doesn't state any</p> <p>6 diagnosis at all. Artificial mesh gross</p> <p>7 examination only. It's a statement that</p> <p>8 specimen was received and that's it. The mesh</p> <p>9 itself wasn't examined.</p> <p>10 Q. It says "A representative section of</p> <p>11 the soft tissue is submitted in Cassette A-1."</p> <p>12 A. Soft tissue, not the mesh.</p> <p>13 Q. "Soft tissue with chronic inflammation</p> <p>14 and focal foreign body giant cell reaction"?</p> <p>15 A. They examined soft tissue, which is</p> <p>16 outside of the mesh.</p> <p>17 Q. So they looked at soft tissue that was</p> <p>18 outside the area of the mesh?</p> <p>19 A. Outside of the mesh. Yes, they looked</p> <p>20 at soft tissue outside the mesh.</p> <p>21 Q. And they found chronic inflammation</p> <p>22 and foreign body giant cell reaction?</p> <p>23 A. Yes.</p> <p>24 Q. And that can -- and that finding can</p> <p>25 occur any time you do surgery in soft tissue?</p>	<p>1 examination and generation of the report.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Setting aside things like when you're</p> <p>4 doing -- someone is going to do a biopsy, if</p> <p>5 you're going to try to assess the degree of</p> <p>6 inflammation in the tissues, you need to look at</p> <p>7 the pathology slides as a pathologist, correct?</p> <p>8 A. To predict what degree I may see, I</p> <p>9 don't have to look at the slides. To assess</p> <p>10 what degree is there, I have to look at slides.</p> <p>11 Q. You can make predictions, but when you</p> <p>12 actually look at the slides, it may be within or</p> <p>13 outside of your predictions, correct?</p> <p>14 A. Yes. Because the prediction will be</p> <p>15 based on my experience and knowledge.</p> <p>16 Q. At your hospital, do you issue</p> <p>17 pathology reports without having reviewed the</p> <p>18 pathology specimen?</p> <p>19 A. No. I do not issue pathology reports</p> <p>20 without reviewing specimens.</p> <p>21 Q. Before you sign your name to a</p> <p>22 pathology report, you will have viewed the</p> <p>23 pathology specimen at your hospital?</p> <p>24 A. Pathology report is generated after</p> <p>25 reviewing specimens.</p>
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<p>1 A. Yes, it can happen immediately, a few</p> <p>2 weeks after surgery.</p> <p>3 Q. Why didn't you look at the specimen</p> <p>4 for Mrs. Huskey?</p> <p>5 A. I wasn't given any.</p> <p>6 Q. I'm sorry?</p> <p>7 A. I didn't receive any specimens for</p> <p>8 her.</p> <p>9 Q. As a pathologist, one of the key</p> <p>10 things you do is look at pathology specimens to</p> <p>11 draw conclusions, correct?</p> <p>12 A. To generate a pathology report, yes, I</p> <p>13 need to look at the specimen.</p> <p>14 Q. To generate a pathology opinion, in</p> <p>15 your normal course of work you look at the</p> <p>16 pathology slides?</p> <p>17 MR. MCCONNELL: Objection.</p> <p>18 A. Not always. Sometimes I'm asked</p> <p>19 questions from clinicians, and we discuss what I</p> <p>20 may see, what by biopsy methodology they can</p> <p>21 use, either it's a fine needle biopsy or it's a</p> <p>22 larger excisional biopsy, and I guide them. Or</p> <p>23 they ask if we take a biopsy, how I can help</p> <p>24 them in the specific differential diagnosis.</p> <p>25 So not always my job is limited to</p>	<p>1 Q. You say under "Mrs. Huskey," take a</p> <p>2 look, the second paragraph under</p> <p>3 "clinico-pathologic correlation," I'm on</p> <p>4 Page 72 --</p> <p>5 A. Yes.</p> <p>6 Q. -- you say "In these samples available</p> <p>7 to me."</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. What samples are you talking about</p> <p>11 there?</p> <p>12 A. Samples of other explanted meshes.</p> <p>13 Q. Not Mrs. Huskey's samples given to</p> <p>14 you?</p> <p>15 A. No.</p> <p>16 Q. Am I correct that you are not talking</p> <p>17 about samples from Mrs. Huskey?</p> <p>18 A. No, I'm not talking about</p> <p>19 Mrs. Huskey's samples. These samples, pertinent</p> <p>20 to either TVT-O meshes or other brands explanted</p> <p>21 from other patients.</p> <p>22 Q. Did you ask for the pathology explant</p> <p>23 in Mrs. Huskey's case?</p> <p>24 A. Yes.</p> <p>25 Q. When did you ask for that?</p>

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<p>1 A. When I was given -- when I was asked 2 to be an expert witness for this case, I said "I 3 need all pathology available for all patients." 4 Q. And when was that for the Huskey case? 5 A. I don't remember now. It was sometime 6 early this year. Because when I received 7 Ms. Edwards', it's been sitting in my office for 8 long time. 9 MR. SNELL: Let's go off the record 10 for a minute. 11 (Off the record discussion.) 12 BY MR. SNELL: 13 Q. Doctor, I believe you earlier 14 testified -- strike that. 15 Did you have a control TVT-O mesh? 16 MR. FABRY: Objection to form. 17 A. You mean control new? 18 BY MR. SNELL: 19 Q. Yes. 20 A. As a control? 21 Q. Yes. 22 A. Yes, I did. 23 Q. Did you do any testing on that control 24 TVT-O mesh? 25 A. I did stretch tests. I put it in</p>	<p>1 purposes of investigating your opinions 2 regarding degradation? 3 A. As I said, I started the test at the 4 time of this report, couldn't complete it. It's 5 still in formalin, some parts. So no completed 6 comparison. 7 Q. And the mesh that you looked at as a 8 control which you exposed to the formalin and 9 then the paraffin was a mesh by another 10 manufacturer? 11 A. Yes. It was AMS. 12 Q. Okay. Was it a pelvic organ prolapse 13 mesh, or a sling mesh? 14 A. It was a sling; exactly look like 15 TVT-O, just without blue filaments. 16 Q. Now, that AMS sling mesh never had 17 tissue on it, am I correct? 18 A. No. 19 Q. No, I'm not correct? 20 A. It never had any tissue on it. 21 Q. Okay. Did that AMS sling mesh -- 22 strike that. 23 Was that AMS sling mesh exposed to 24 proteins in the human body? 25 A. It was not exposed to proteins.</p>
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<p>1 formalin, I think I still had parts of it in 2 formalin mand then put it in paraffin. 3 Q. Are there any pictures or results of 4 any testing you did on that control mesh? 5 A. As I told you, that for that specific 6 block it was difficult, filaments were floating 7 out, so I ended up with just non-TVT-O. I can 8 section it again, but at the time of the report 9 the sections floated. 10 Q. So you didn't compare Mrs. Edwards' 11 TVT-O mesh to a TVT-O control mesh, correct? 12 MR. FABRY: Objection. Form. 13 A. For degradation? 14 BY MR. SNELL: 15 Q. For anything. 16 A. No. The only thing I was testing new 17 was degradation. 18 Q. So we're clear, did you compare 19 Mrs. Edwards' TVT-O mesh to a TVT-O control mesh 20 for the purposes of your degradation analyses? 21 A. Not at the time of the report. The 22 experiment is still ongoing. 23 Q. Have you made -- well, have you done 24 it as we sit here today, compared Mrs. Edwards' 25 TVT-O mesh to a control TVT-O mesh for the</p>	<p>1 That's the whole purpose of the control, not to 2 get it exposed. Exposed to everything else but 3 the body. 4 Q. Okay. And how long was that control 5 AMS mesh sling exposed to formalin? 6 A. The latest test came after one month 7 exposure to formalin. 8 Q. So, for example, Mrs. Edwards' mesh 9 was in formalin for over a year? 10 A. Yes. But I had other patients which 11 had their mesh only for 72 hours in formalin, 12 especially at St. Michael's, or other samples 13 which are coming in paraffin blocks, they're 14 processed in 48 to 72 hours. 15 Q. Did you have a control mesh sample 16 which had been exposed to formalin for the same 17 length of time that Mrs. Edwards' mesh was 18 exposed to formalin? 19 A. Actually had it longer, because her 20 initial H&amp;E sections were exposed to formalin 21 within reasonable lab time, which is 48 to 72 22 hours. The specimen I processed, it had over a 23 year exposure to formalin. But the slides which 24 were cut initially, original, they were exposed 25 to formalin only four days. The lab procedures</p>

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<p>1 say usually within three days.</p> <p>2 Q. For the processing you did, your</p> <p>3 control was exposed to formalin for a month at</p> <p>4 the most?</p> <p>5 A. Yes.</p> <p>6 Q. What's the minimum that your control</p> <p>7 was exposed to formalin for?</p> <p>8 A. 48 hours, 48 to 72 hours. I just put</p> <p>9 it in the same bucket with regular specimens.</p> <p>10 Q. On the H&amp;E slides from Emory which you</p> <p>11 looked at, the three slides, that's the sum</p> <p>12 total of slides you've looked at from Emory for</p> <p>13 Mrs. Edwards?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And did you see this bark,</p> <p>16 degradation bark, in those three H&amp;E slides from</p> <p>17 Emory?</p> <p>18 A. I've seen bark in all explanted</p> <p>19 meshes, in all slides. I don't remember</p> <p>20 anything, so it must be there. I mean I would</p> <p>21 have to -- the only time when I don't see the</p> <p>22 bark when there are no filaments. If those</p> <p>23 slides contain the bark -- the filaments, I saw</p> <p>24 the bark.</p> <p>25 Q. As you sit here today, do you know</p>	<p>1 degradation?</p> <p>2 A. I observed the staining of the bark</p> <p>3 and polarized it.</p> <p>4 Q. Is it generally accepted in the</p> <p>5 medical community to use immunohistochemical</p> <p>6 staining to ascertain the amount that the stain</p> <p>7 soaks up in material?</p> <p>8 A. Yes, it's called measuring protein</p> <p>9 expression. By the intensity of staining you</p> <p>10 measure amount of expression of a protein.</p> <p>11 Q. And is there any medical literature</p> <p>12 that reports on the degree or amount of stain</p> <p>13 which is soaked up by polypropylene that you've</p> <p>14 located?</p> <p>15 A. No. It doesn't soak anything.</p> <p>16 Q. I'm sorry?</p> <p>17 A. It does not soak any fluids. It's</p> <p>18 hydrophobic.</p> <p>19 Q. Was there any inflammation from the</p> <p>20 degradation that you saw in Mrs. Edwards' case?</p> <p>21 A. Repeat the question, please?</p> <p>22 Inflammation?</p> <p>23 Q. Was there inflammation from the</p> <p>24 degradation you claim occurred in Mrs. Edwards'</p> <p>25 case?</p>
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<p>1 whether you saw bark in those three H&amp;E slides</p> <p>2 from Emory?</p> <p>3 A. I don't remember.</p> <p>4 Q. Did you take photographs of what you</p> <p>5 saw in those three slides from Emory?</p> <p>6 A. I can't -- have some pictures of those</p> <p>7 slides. I'm not sure if they're in the report</p> <p>8 or they're in different ones. The quality is</p> <p>9 visually worse than from the previous slides.</p> <p>10 Q. Did you --</p> <p>11 A. I did not note a difference between my</p> <p>12 sections and those, Emory. If there was a</p> <p>13 difference I would have noticed, and remembered</p> <p>14 that.</p> <p>15 Q. Did you make any notes as you reviewed</p> <p>16 the slides?</p> <p>17 A. Yes. They all were put in drafts, and</p> <p>18 then the -- the first pathology report, and then</p> <p>19 I continued reviewing them, and they were put in</p> <p>20 the expert report.</p> <p>21 MR. SNELL: Let's go off the record.</p> <p>22 (Off the record discussion.)</p> <p>23 BY MR. SNELL:</p> <p>24 Q. In Mrs. Edwards' case, what tests, if</p> <p>25 any, did you do to determine whether there was</p>	<p>1 A. Well, I see degradation and I see</p> <p>2 inflammation at the same time. Specifically</p> <p>3 determine what is triggering that inflammation</p> <p>4 or if there are multiple triggers is impossible,</p> <p>5 because there can be multiple triggers. I see</p> <p>6 degradation and I see inflammation all occurring</p> <p>7 at the same time.</p> <p>8 Q. Did you see a higher concentration of</p> <p>9 inflammatory cells near the area of this bark,</p> <p>10 as you call it, in Mrs. Edwards' case?</p> <p>11 A. Yes. All inflammatory cells</p> <p>12 surround -- concentrated around the filaments.</p> <p>13 The bark is at the surface of the filaments.</p> <p>14 Q. Show me an example in your expert</p> <p>15 report where there's a higher concentration of</p> <p>16 inflammatory cells at the bark, and where there</p> <p>17 are no inflammatory cells away from the mesh.</p> <p>18 A. This (indicating). This is the bark,</p> <p>19 here's inflammation cells, these are no</p> <p>20 inflammation cells.</p> <p>21 MR. FABRY: What image are you looking</p> <p>22 at, Doctor?</p> <p>23 THE WITNESS: This is Page 37, Figure</p> <p>24 19b.</p> <p>25 BY MR. SNELL:</p>

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<p>1 Q. Page 37, Figure 19b is not 2 Mrs. Edwards, correct? 3 A. No. If you want me to go specifically 4 to Mrs. Edwards, figure -- Page 70, Figure 5 TE10a, see these cells? These are all 6 inflammatory cells, and this is scar. So no 7 inflammatory cells here. All inflammatory cells 8 are right against the inflammatory cells. This 9 is the bark. 10 Same thing here, Figure 68, Figure 11 TE9a, bark, inflammatory cells. Tissue is 12 collagen (indicating). 13 Q. Hold on. 14 In Figure TE9a, there are inflammatory 15 cells away from what you've labeled as 16 degradation bark, correct? 17 A. So this is inflammatory cells. 18 Q. And there are inflammatory cells to 19 the left of that as well, correct? 20 A. Well, there might be another filament 21 here. I didn't look. 22 Q. I don't want might. 23 These dark dots to the left of the 24 degradation bark, to the left of where you've 25 labeled tissue, are inflammatory cells, correct?</p>	<p>1 calculations to look at the inflammatory cells 2 in a certain power field to see whether there 3 was a statistically significant difference in 4 the areas next to the mesh or away from the 5 mesh? 6 A. No. This is observation, it doesn't 7 need specific calculations. If I do 8 calculations I have to -- this is done for 9 purpose of 95 percent accuracy or certainty. 10 For just descriptive, I don't need to do this 11 testing, otherwise I would be doing my reports 12 forever for one patient. 13 MR. SNELL: Let's go off the record. 14 (Off the record discussion.) 15 BY MR. SNELL: 16 Q. The inflammatory cells that you saw in 17 the tissues of Mrs. Edwards' explants, what are 18 the different processes or causes of those 19 inflammatory cells being present? 20 A. Inflammation can happen to foreign 21 body. If a foreign body is inert, the amount of 22 inflammation is minimal to no inflammation at 23 all. So the foreign body should release some 24 chemicals to be recognized as a foreign. That's 25 where I think we can think about degradation,</p>
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<p>1 A. Yes, they are, in this specific 2 photograph. 3 Q. All right. 4 A. Now if we go back to this stain. 5 Q. You're on TE7b? 6 A. 66. Figure TE7b, this upper part, two 7 crossing filaments, inflammatory cells are here, 8 there's not much inflammatory cells away. The 9 bark is here, bark is there (indicating). 10 Q. The blue dots are the inflammatory 11 cells? 12 A. Yes. 13 Q. And there are inflammatory cells 14 throughout all of the tissue in-between the mesh 15 filaments in the top and the bottom, correct? 16 A. Scattered, yet not concentrated. 17 Q. So in the left corner, can you see 18 concentrations of inflammatory cells? 19 A. Oh, this is just tissue artifact, just 20 folded. 21 Q. Just tissue artifact? 22 A. Yes. That specific -- yes, there 23 could be, but in that specific picture it's an 24 artifact. 25 Q. Did you quantify it in any</p>	<p>1 release of molecules off the surface. 2 Then there can be bacteria which also 3 trigger inflammatory responses. 4 Q. Why does the bark take up the stain? 5 A. Why barks takes the stain? It's 6 porosity. The porous, cracks, they just trap 7 histological stains specifically. You can do it 8 green, blue, black, any dye will stay there. 9 I've done it green, I've done it red, I've done 10 it any color. 11 Q. For the degradation analyses, why 12 didn't you do any scanning electron microscopy 13 on Mrs. Edwards? 14 A. I don't think it contributes. It 15 doesn't answer any questions. 16 Q. Can you say that -- are you saying 17 that there is -- if one were to look at 18 Mrs. Edwards' explants under scanning electron 19 microscope, there would not be any findings of 20 significance? 21 A. It will be finding of a cracking. I 22 can look in microscope just with a reflected 23 light. I can -- I have actually done pictures 24 of cracks from the surface in regular 25 microscope, they look exactly like scanning</p>

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<p>1 electron microscopy.</p> <p>2 Q. You didn't do that for Mrs. Edwards?</p> <p>3 A. No, because it doesn't contribute. It</p> <p>4 shows cracks, but then you're stuck with if the</p> <p>5 cracks is inspissated in body protein or</p> <p>6 polypropylene, I cannot analyze what the</p> <p>7 material is on the surface, in the</p> <p>8 cross-sections I can't analyze it.</p> <p>9 Q. The crack can be from the body's</p> <p>10 proteins, that's one source?</p> <p>11 A. Yes.</p> <p>12 Q. And another source for your opinion is</p> <p>13 that the cracks can be from degraded</p> <p>14 polypropylene?</p> <p>15 A. Yes. So if you see cracked material</p> <p>16 in the surface, it can be either polypropylene</p> <p>17 crack or protein.</p> <p>18 Q. Did you attempt to isolate this bark</p> <p>19 that you opine is in the slides and chemically</p> <p>20 analyze it?</p> <p>21 A. No.</p> <p>22 Q. Are any of the Plaintiffs' experts</p> <p>23 currently doing that analysis?</p> <p>24 A. They're comparing scratched anodes,</p> <p>25 scratched filaments. But to me, I can polarize</p>	<p>1 is collagen, that's how it looks under polarized</p> <p>2 light.</p> <p>3 MR. FABRY: For the record, Doctor,</p> <p>4 which image are we looking at?</p> <p>5 THE WITNESS: 70, Page 70, picture</p> <p>6 TE10a.</p> <p>7 MR. FABRY: That would be an image</p> <p>8 specifically from --</p> <p>9 MR. SNELL: Hold on. This is my exam.</p> <p>10 If you want to ask those questions, you can feel</p> <p>11 free.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. What other tissue cells light up</p> <p>14 during polarized light?</p> <p>15 A. Cells will not polarize. There are</p> <p>16 some proteins which can polarize light, some.</p> <p>17 This would be collagen, amyloid, other proteins.</p> <p>18 The degree of polarization is much lower.</p> <p>19 Why are we discussing this? There are</p> <p>20 granules, blue granules which your company</p> <p>21 inserted and it's right in the bark. This is</p> <p>22 useless discussion.</p> <p>23 Q. Where do you see the blue granules?</p> <p>24 A. Here, Page 71, blue granules are in</p> <p>25 the bark. This is polypropylene.</p>
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<p>1 it. If I see that the bark is synthetic,</p> <p>2 polarized acts as a polypropylene optically, it</p> <p>3 is a polypropylene. So this is the type of</p> <p>4 chemical analysis I do under microscope. I</p> <p>5 analyze optical properties of the material.</p> <p>6 Q. Actually optical properties, when</p> <p>7 you're looking at polarized light, is not a</p> <p>8 chemical analysis?</p> <p>9 A. No. But it reflects chemical</p> <p>10 composition.</p> <p>11 Q. And you know that polarized light will</p> <p>12 reflect all things besides polypropylene,</p> <p>13 correct?</p> <p>14 A. Say it again?</p> <p>15 Q. If you look at slides of tissue under</p> <p>16 polarized light, a polypropylene mesh is not the</p> <p>17 only thing that will light up and be shown in</p> <p>18 the polarization, correct?</p> <p>19 A. Foreign bodies, most foreign bodies</p> <p>20 able to polarize light will polarize.</p> <p>21 Q. Have you looked at the medical</p> <p>22 literature to see whether collagen reflects</p> <p>23 under polarized light?</p> <p>24 A. Collagen polarizes light to much less</p> <p>25 a degree. You can see it in the pictures. This</p>	<p>1 Q. So --</p> <p>2 A. Figure TE10b.</p> <p>3 MR. SNELL: Are you testifying over</p> <p>4 there, Margaret?</p> <p>5 MS. THOMPSON: To Andy.</p> <p>6 A. This is Figure TE10b. See the blue</p> <p>7 granules? This is bark. So the inner layers of</p> <p>8 the bark are staining lightly, because the</p> <p>9 pores, the cracks are small, they do not absorb</p> <p>10 as much dye. But also degradation process is</p> <p>11 not as advanced to destroy this granule.</p> <p>12 Once you go towards the surface, the</p> <p>13 cracks open, the pores are larger, they absorb</p> <p>14 more dye, therefore staining is darker, and the</p> <p>15 blue granules lose their color.</p> <p>16 This is logical. I mean how much</p> <p>17 better you can get?</p> <p>18 BY MR. SNELL:</p> <p>19 Q. By what process does these blue --</p> <p>20 what do you call them -- granules lose their</p> <p>21 color?</p> <p>22 A. Degradation. They degrade.</p> <p>23 Q. How?</p> <p>24 A. The same way as -- well, specific</p> <p>25 chemical process?</p>

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<p>1 Q. Yes. Are you talking oxidation? What</p> <p>2 are you talking about?</p> <p>3 A. This has to be studied. I'm not a</p> <p>4 material scientist. I don't think anybody knows</p> <p>5 exactly. There is hypothesis of oxidation and</p> <p>6 reactive species, but I mean I'm not a materials</p> <p>7 scientist.</p> <p>8 Q. There's people who analyzed whether</p> <p>9 there is alleged oxidation, and they found that</p> <p>10 there is no oxidation. You're aware of that</p> <p>11 leak research, correct?</p> <p>12 A. I don't know. This is polypropylene,</p> <p>13 it's completely different, behaving differently</p> <p>14 than non-degraded polypropylene. And it doesn't</p> <p>15 form by formalin alone, it forms in vivo.</p> <p>16 Q. Slide TE10b, what power or</p> <p>17 magnification was that at?</p> <p>18 A. This is 100 oil immersion. These are</p> <p>19 all pictures of degradation of 100 objective oil</p> <p>20 immersion.</p> <p>21 Q. That was under a light microscope, or</p> <p>22 an electron microscope?</p> <p>23 A. Light.</p> <p>24 MR. SNELL: Go off.</p> <p>25 (Off the record discussion.)</p>	<p>1 Number 9, your pathology report, to the</p> <p>2 deposition today, did you?</p> <p>3 A. No. I believe it was served to you</p> <p>4 before.</p> <p>5 MR. SNELL: I'll make an application</p> <p>6 to come back.</p> <p>7 That's all the questions I have for</p> <p>8 now.</p> <p>9 Let me just make one thing.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. Doctor, I want you to preserve all of</p> <p>12 the materials that we discussed that you have at</p> <p>13 your lab and that's part of your file, all the</p> <p>14 photos, all the samples, all the exemplars, the</p> <p>15 controls.</p> <p>16 You understand that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay.</p> <p>19 A. Pertinent to TVT-O litigation?</p> <p>20 Q. Pertinent to all, because my request</p> <p>21 goes beyond TVT-O.</p> <p>22 A. I cannot preserve if I'm requested to</p> <p>23 supply specimens for the litigation. If I</p> <p>24 receive the same request from another company, I</p> <p>25 have to supply it to them.</p>
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<p>1 (Whereupon, Iakovlev Exhibit Number 9,</p> <p>2 Dr. Iakovlev's pathology report for</p> <p>3 Mrs. Edwards' specimen, was marked for</p> <p>4 identification.)</p> <p>5 BY MR. SNELL:</p> <p>6 Q. Doctor, I'm going to attach Exhibit</p> <p>7 Number 9 to your deposition.</p> <p>8 A. Yes.</p> <p>9 Q. This is your expert report in</p> <p>10 Mrs. Edwards' case?</p> <p>11 A. No. This is pathology report.</p> <p>12 Q. Strike that.</p> <p>13 Identify for the record what Exhibit</p> <p>14 Number 9 is.</p> <p>15 A. It's a pathology report for</p> <p>16 Mrs. Edwards' specimen.</p> <p>17 Q. Did you prepare that report?</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: Just note for the record</p> <p>20 we received this about 20 minutes ago.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. Let me take a look at that, Doctor,</p> <p>23 because I don't have a separate copy.</p> <p>24 A. (Handing).</p> <p>25 Q. You didn't bring a copy of Exhibit</p>	<p>1 Q. That's fine.</p> <p>2 But -- so your expert reports and your</p> <p>3 pathology reports you've issued on other</p> <p>4 litigation meshes, you still have those</p> <p>5 pathology reports?</p> <p>6 A. Pathology reports have confidential</p> <p>7 names of the patients. I can provide pictures.</p> <p>8 MR. FABRY: Right now we're not having</p> <p>9 a discussion about what will be produced. That</p> <p>10 will be a separate discussion.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. I'm just asking you to preserve --</p> <p>13 A. I will preserve everything I can.</p> <p>14 MR. SNELL: Thank you.</p> <p>15 MR. FABRY: No questions. We'll</p> <p>16 reserve our questions for trial.</p> <p>17 Thank you.</p> <p>18 (Whereupon, the deposition was</p> <p>19 concluded at 4:28 p.m.)</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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Page 310	Page 312
1 COMMONWEALTH OF MASSACHUSETTS )	1 -----
2 SUFFOLK, SS. )	2 E R R A T A
3 I, MAUREEN O'CONNOR POLLARD, RMR, CLR,	3 -----
4 and Notary Public in and for the Commonwealth of	4 PAGE LINE CHANGE
5 Massachusetts, do certify that on the 18th day	5 REASON: _____
6 of March, 2014, at 8:14 o'clock, the person	6 REASON: _____
7 above-named was duly sworn to testify to the	7 REASON: _____
8 truth of their knowledge, and examined, and such	8 REASON: _____
9 examination reduced to typewriting under my	9 REASON: _____
10 direction, and is a true record of the testimony	10 REASON: _____
11 given by the witness. I further certify that I	11 REASON: _____
12 am neither attorney, related or employed by any	12 REASON: _____
13 of the parties to this action, and that I am not	13 REASON: _____
14 a relative or employee of any attorney employed	14 REASON: _____
15 by the parties hereto, or financially interested	15 REASON: _____
16 in the action.	16 REASON: _____
17 In witness whereof, I have hereunto	17 REASON: _____
18 set my hand this 30th day of March, 2014.	18 REASON: _____
19	19 REASON: _____
20	20 REASON: _____
21 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC	21 REASON: _____
22 Realtime Systems Administrator	22 REASON: _____
23 CSR #149108	23 REASON: _____
24	24 REASON: _____
25	25 REASON: _____

  

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1 INSTRUCTIONS TO WITNESS	1 ACKNOWLEDGMENT OF DEPONENT
2	2
3 Please read your deposition over	3 I, _____, do
4 carefully and make any necessary corrections.	4 Hereby certify that I have read the foregoing
5 You should state the reason in the appropriate	5 pages, and that the same is a correct
6 space on the errata sheet for any corrections	6 transcription of the answers given by me to the
7 that are made.	7 questions therein propounded, except for the
8 After doing so, please sign the	8 corrections or changes in form or substance, if
9 errata sheet and date it. It will be attached	9 any, noted in the attached Errata Sheet.
10 to your deposition.	10
11 It is imperative that you return	11
12 the original errata sheet to the deposing	12
13 attorney within thirty (30) days of receipt of	13
14 the deposition transcript by you. If you fail	14
15 to do so, the deposition transcript may be	15
16 deemed to be accurate and may be used in court.	16 Subscribed and sworn
17	17 To before me this
18	18 _____ day of _____, 20____.
19	19 My commission expires: _____
20	20
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23	23
24	24
25	25

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1	LAWYER'S NOTES	
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